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21 USC CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT 01/06/03

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TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

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CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 321d, 355b, 453, 457, 466, 467, 467f, 601, 607, 620, 679, 802, 811, 823, 829, 830, 902, 1033, 1049, 1052, 1401, 1402, 1403, 1601 of this title; title 7 sections 136a−1, 136v, 138i, 1431c, 5341, 6519, 7653, 8401; title 15 sections 70j, 1261, 1263, 1277, 1459, 1460, 2057a, 2057b, 2079; title 18 sections 42, 983; title 19 section 2578a; title 26 sections 170, 4817; title 35 sections 155, 156, 271, 287; title 42

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21 USC SUBCHAPTER I − SHORT TITLE 01/06/03

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21 USC Sec. 301 01/06/03

−EXPCITE−

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Sec. 301. Short title

−STATUTE−

This chapter may be cited as the Federal Food, Drug, and Cosmetic

Act.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 1, 52 Stat. 1040.)

−MISC1−

EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, Sec. 1, 2, 53 Stat. 853, 854,

provided that:

"(Sec. 1) (a) The effective date of the following provisions of the Federal Food, Drug, and Cosmetic Act is hereby postponed until January 1, 1940: Sections 402(c) (342(c) of this title); 403(e)(1) (343(e)(1) of this title); 403(g), (h), (i), (j), and (k) (343(g) to (k) of this title); 501(a), (4) (351(a)(4) of this title); 502(b), (d), (e), (f), (g), and (h) (352(b), (d) to (h) of this title); 601(e) (361(e) of this title); and 602(b) (362(b) of this title).

"(b) The Secretary of Agriculture shall promulgate regulations further postponing to July 1, 1940 the effective date of the provisions of sections 403(e)(1) (343(e)(1) of this title); 403(g), (h), (i), (j), and (k) (343(g) to (k)); 502(b), (d), (e), (f), (g), and (h) (352(b), (d) to (h) of this title); and 602(b) (362(b) of this title) of such Act with respect to lithographed labeling which was manufactured prior to February 1, 1939, and to containers bearing labeling which, prior to February 1, 1939, was lithographed, etched, stamped, pressed, printed, fused or blown on or in such containers, where compliance with such provisions would be unduly burdensome by reason of causing the loss of valuable stocks of such labeling or containers, and where such postponement would not prevent the public interest being adequately served: Provided, That in no case shall such regulations apply to labeling which would not have complied with the requirements of the Food and Drugs Act of June 30, 1906, as amended.

"Sec. 2. (a) The provisions of section 8 (section 10 of this title), paragraph fifth, under the heading 'In the case of food:', of the Food and Drugs Act of June 30, 1906, as amended, and regulations promulgated thereunder, and all other provisions of such Act to the extent that they may relate to the enforcement of such section 8 (section 10 of this title) and of such regulations, shall remain in force until January 1, 1940.

"(b) The provisions of such Act of June 30, 1906, as amended, (sections 1 to 5, 7 to 15, and 372a of this title) to the extent that they impose, or authorize the imposition of, any requirement imposed by section 403(k) of the Federal Food, Drug, and Cosmetic Act (section 343(k) of this title), shall remain in force until January 1, 1940.

"(c) Notwithstanding the provisions of section 1 of this Act, such section shall not apply −

"(1) to the provisions of section 502(d) and (e) of the Federal Food, Drug, and Cosmetic Act (352(d), (e) of this title), insofar as such provisions relate to any substance named in section 8 (section 10 of this title), paragraph second, under the heading 'In the case of drugs:', of the Food and Drugs Act of June 30, 1906, as amended, or a derivative of any such substance; or

"(2) to the provisions of section 502(b), (d), (e), (f), (g), and (h) of the Federal Food, Drug, and Cosmetic Act (352(b), (d) to (h) of this title), insofar as such provisions relate to drugs to which section 505 (355 of this title) of such Act applies."

EFFECTIVE DATE

Section 902(a) of act June 25, 1938, provided that: "This Act (enacting this chapter and repealing sections 1 to 5 and 7 to 15 of this title), shall take effect twelve months after the date of its enactment (June 25, 1938). The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1−15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: Provided, That the provisions of section 701 (section 371 of this title) shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403(i) (section 343(i) of this title) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401 (section 341 of this title): Provided further, That sections 502(j), 505, and 601(a) (sections 352(j), 355, 361(a), respectively of this title), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601(a) (section 361(a) of this title), relates, such cosmetic shall not,

prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: Provided further, That the Act of March 4, 1923 (U.S.C., 1934 ed., title 21, sec. 6 (section 321a of this title); 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U.S.C., 1934 ed., title 21, sec. 10 (section 321b of this title); 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U.S.C. 1934 ed., Sup. III, title 21, sec. 14a (section 372a of this title)) shall remain in force and effect and be applicable to the provisions of this Act."

HAZARDOUS SUBSTANCES

Federal Hazardous Substances Act as not modifying this chapter, see Pub. L. 86−613, Sec. 18, July 12, 1960, 74 Stat. 380, set out as an Effect Upon Federal and State Laws note under section 1261 of Title 15, Commerce and Trade.

SHORT TITLE OF 2002 AMENDMENTS

Pub. L. 107−281, Sec. 1, Nov. 6, 2002, 116 Stat. 1992, provided that: "This Act (amending sections 360cc and 360ee of this title and enacting provisions set out as a note under section 360ee of this title) may be cited as the 'Rare Diseases Orphan Product Development Act of 2002'."

Pub. L. 107−250, Sec. 1(a), Oct. 26, 2002, 116 Stat. 1588, provided that: "This Act (enacting sections 379i and 379j of this title and section 289g−3 of Title 42, The Public Health and

Welfare, amending sections 321, 331, 333, 335a, 352, 353, 360, 360c, 360e, 360m, and 374 of this title, and enacting provisions set out as notes under sections 352, 360e, 360j, 360l, 379i, and 379j of this title and section 289g−3 of Title 42) may be cited as the 'Medical Device User Fee and Modernization Act of 2002'."

Pub. L. 107−188, title V, Sec. 501, June 12, 2002, 116 Stat. 687, provided that: "This subtitle (subtitle A (Sec. 501−509) of title V of Pub. L. 107−188, amending sections 356b, 379g, and 379h of this title and enacting provisions set out as notes under sections 356b and 379g of this title) may be cited as the 'Prescription Drug User Fee Amendments of 2002'."

Pub. L. 107−109, Sec. 1, Jan. 4, 2002, 115 Stat. 1408, provided that: "This Act (enacting sections 355b and 393a of this title and section 284m of Title 42, The Public Health and Welfare, amending sections 321, 355, 355a, and 379h of this title and sections 282, 284k, 284l, 285a−2, and 290b of Title 42, and enacting provisions set out as notes under sections 355 and 355a of this title and sections 284m and 289 of Title 42) may be cited as the 'Best Pharmaceuticals for Children Act'."

SHORT TITLE OF 2000 AMENDMENT

Pub. L. 106−387, Sec. 1(a) (title VII, Sec. 745(a)), Oct. 28, 2000, 114 Stat. 1549, 1549A−35, provided that: "This section (enacting section 384 of this title, amending sections 331, 333, and 381 of this title, and enacting provisions set out as a note under section 384 of this title) may be cited as the 'Medicine Equity and Drug Safety Act of 2000'."

Pub. L. 106−387, Sec. 1(a) (title VII, Sec. 746(a)), Oct. 28, 2000, 114 Stat. 1549, 1549A−40, provided that: "This section (amending section 381 of this title and enacting provisions set out as a note under section 381 of this title) may be cited as the 'Prescription Drug Import Fairness Act of 2000'."

SHORT TITLE OF 1998 AMENDMENT

Pub. L. 105−324, Sec. 1, Oct. 30, 1998, 112 Stat. 3035, provided that: "This Act (amending sections 321 and 346a of this title) may be cited as the 'Antimicrobial Regulation Technical Corrections Act of 1998'."

SHORT TITLE OF 1997 AMENDMENT

Pub. L. 105−115, Sec. 1(a), Nov. 21, 1997, 111 Stat. 2296, provided that: "This Act (enacting sections 343−3, 353a, 355a, 356 to 356c, 360m, 360aaa to 360aaa−6, 360bbb to 360bbb−2, 379k, 379l, 379o, 379r, 379s, 379v, 396, and 397 of this title and sections 247b−8 and 299a−3 of Title 42, The Public Health and Welfare, amending sections 321, 331, 334, 335a, 343, 348, 351 to 353, 355, 360, 360b to 360e, 360g, 360i, 360j, 360l, 360aa to 360cc, 360ee, 371, 374, 379a, 379g, 379h, 381 to 383, 393, and 802 of this title, section 45C of Title 26, Internal Revenue Code, section 156 of Title 35, Patents, section 8126 of Title 38, Veterans' Benefits, and sections 262, 263a, and 282 of Title 42, repealing sections 356 and 357 of this title, and enacting provisions set out as notes under sections 321, 348, 351, 352, 353a, 355 to 356b, 360i, 360l, 360m, 360aaa, 371, 379g, 379h, 379k, and 393 of this title and sections 247b−8 and 282 of Title 42) may be cited as the 'Food and

Drug Administration Modernization Act of 1997'."

SHORT TITLE OF 1996 AMENDMENTS

Pub. L. 104−250, Sec. 1(a), Oct. 9, 1996, 110 Stat. 3151, provided that: "This Act (enacting section 354 of this title, amending sections 331, 353, and 360b of this title, and enacting provisions set out as notes under section 360b of this title) may be cited as the 'Animal Drug Availability Act of 1996'."

Pub. L. 104−170, title IV, Sec. 401(a), Aug. 3, 1996, 110 Stat. 1513, provided that: "This title (amending sections 321, 331, 333, 342, and 346a of this title) may be cited as the 'Food Quality Protection Act of 1996'."

(Another "Food Quality Protection Act of 1996", was enacted by Pub. L. 104−170, Sec. 1, 110 Stat. 1489, which is set out as a note under section 136 of Title 7, Agriculture.)

Pub. L. 104−134, title II, Sec. 2101(a), Apr. 26, 1996, 110 Stat. 1321−313, provided that: "This chapter (chapter 1A (Sec. 2101−2105) of title II of Pub. L. 104−134, enacting section 382 of this title and amending sections 331 and 381 of this title and section 262 of Title 42, The Public Health and Welfare) may be cited as the 'FDA Export Reform and Enhancement Act of 1996'."

SHORT TITLE OF 1994 AMENDMENTS

Pub. L. 103−417, Sec. 1(a), Oct. 25, 1994, 108 Stat. 4325, provided that: "This Act (enacting sections 343−2 and 350b of this title and section 287c−11 of Title 42, The Public Health and Welfare, amending sections 321, 331, 342, 343, and 350 of this title and section 281 of Title 42, and enacting provisions set out

as notes under sections 321 and 343 of this title) may be cited as the 'Dietary Supplement Health and Education Act of 1994'."

Pub. L. 103−396, Sec. 1, Oct. 22, 1994, 108 Stat. 4153, provided that: "This Act (amending sections 331, 343−1, 360b, and 371 of this title and enacting provisions set out as notes under section 360b of this title) may be cited as the 'Animal Medicinal Drug Use Clarification Act of 1994'."

SHORT TITLE OF 1993 AMENDMENT

Pub. L. 103−80, Sec. 1, Aug. 13, 1993, 107 Stat. 773, provided that: "This Act (amending sections 321, 331 to 333, 334, 335b, 341 to 343, 346a, 350a, 352, 355 to 358, 360b to 360e, 360i, 360cc, 360hh to 360ss, 361, 371, 372, 373, 374, 376, 379e, and 381 of this title and section 263b of Title 42, The Public Health and Welfare, and enacting provisions set out as a note under section 343 of this title) may be cited as the 'Nutrition Labeling and Education Act Amendments of 1993'."

SHORT TITLE OF 1992 AMENDMENTS

Pub. L. 102−571, title I, Sec. 101(a), Oct. 29, 1992, 106 Stat. 4491, provided that: "This title (enacting sections 379g and 379h of this title, transferring sections 372a, 376, and 379c of this title to sections 376, 379e and 379f, respectively, of this title, amending sections 321, 331, 342, 343, 346a, 351, 352, 360j, 361, 362, 453, 601, and 1033 of this title, enacting provisions set out as notes under section 379g of this title, and amending provisions set out as notes under sections 343 and 343−1 of this title) may be cited as the 'Prescription Drug User Fee Act of 1992'."

Pub. L. 102−571, title II, Sec. 201, Oct. 29, 1992, 106 Stat. 4500, provided that: "This title (enacting provisions set out as notes under sections 343 and 393 of this title and amending provisions set out as notes under sections 343 and 343−1 of this title) may be cited as the 'Dietary Supplement Act of 1992'."

Pub. L. 102−353, Sec. 1(a), Aug. 26, 1992, 106 Stat. 941, provided that: "This Act (amending sections 333, 353, and 381 of this title and enacting provisions set out as a note under section 353 of this title) may be cited as the 'Prescription Drug Amendments of 1992'."

Pub. L. 102−300, Sec. 1(a), June 16, 1992, 106 Stat. 238, provided that: "This Act (amending sections 321, 331, 334, 346a, 352, 353, 356, 357, 360c, 360d, 360g to 360i, 360l, 360mm, 371 to 372a, 376, and 381 of this title and section 262 of Title 42, The Public Health and Welfare and enacting and amending provisions set out as notes under section 360i of this title) may be cited as the 'Medical Device Amendments of 1992'."

Pub. L. 102−282, Sec. 1(a), May 13, 1992, 106 Stat. 149, provided that: "This Act (enacting sections 335a to 335c of this title, amending sections 321, 336, 337, and 355 of this title, and enacting provisions set out as notes under section 335a of this title) may be cited as the 'Generic Drug Enforcement Act of 1992'."

SHORT TITLE OF 1990 AMENDMENTS

Pub. L. 101−635, Sec. 1(a), Nov. 28, 1990, 104 Stat. 4583, provided that: "This Act (enacting sections 379b to 379d and 394

of this title) may be cited as the 'Food and Drug Administration Revitalization Act'."

Pub. L. 101−629, Sec. 1(a), Nov. 28, 1990, 104 Stat. 4511, provided that: "This Act (enacting sections 360l and 383 of this title, amending sections 321, 333, 351, 353, and 360c to 360j of this title and sections 263b to 263n of Title 42, The Public Health and Welfare, redesignating sections 263b to 263n of Title 42 as sections 360gg to 360ss of this title, repealing section 263b of Title 42, and enacting provisions set out as notes under sections 333, 360c, 360i, 360j, 360hh and 383 of this title) may be cited as the 'Safe Medical Devices Act of 1990'."

Pub. L. 101−535, Sec. 1(a), Nov. 8, 1990, 104 Stat. 2353, provided that: "This Act (enacting section 343−1 of this title, amending sections 321, 337, 343, 345, and 371 of this title, and enacting provisions set out as notes under sections 343 and 343−1 of this title) may be cited as the 'Nutrition Labeling and Education Act of 1990'."

SHORT TITLE OF 1988 AMENDMENTS

Pub. L. 100−670, Sec. 1(a), Nov. 16, 1988, 102 Stat. 3971, provided that: "This Act (amending sections 321, 353, and 360b of this title, section 2201 of Title 28, Judiciary and Judicial Procedure, and sections 156 and 271 of Title 35, Patents, and enacting provisions set out as notes under section 360b of this title) may be cited as the 'Generic Animal Drug and Patent Term Restoration Act'."

Pub. L. 100−607, title V, Sec. 501, Nov. 4, 1988, 102 Stat. 3120,

provided that: "This title (enacting section 393 of this title, amending sections 5315 and 5316 of Title 5, Government Organization and Employees, and enacting provisions set out as notes under section 393 of this title) may be cited as the 'Food and Drug Administration Act of 1988'."

Pub. L. 100−293, Sec. 1(a), Apr. 22, 1988, 102 Stat. 95, provided that: "This Act (amending sections 331, 333, 353, and 381 of this title and enacting provisions set out as notes under section 353 of this title) may be cited as the 'Prescription Drug Marketing Act of 1987'."

Pub. L. 100−290, Sec. 1, Apr. 18, 1988, 102 Stat. 90, provided that: "This Act (amending sections 360bb and 360ee of this title, enacting provisions set out as a note under section 360aa of this title, and amending provisions set out as a note under section 236 of Title 42, The Public Health and Welfare) may be cited as the 'Orphan Drug Amendments of 1988'."

SHORT TITLE OF 1986 AMENDMENT

Pub. L. 99−660, title I, Sec. 101(a), Nov. 14, 1986, 100 Stat. 3743, provided that: "This title (enacting section 382 of this title, amending sections 241 and 262 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 333 of this title and section 262 of Title 42) may be cited as the 'Drug Export Amendments Act of 1986'."

SHORT TITLE OF 1985 AMENDMENT

Pub. L. 99−91, Sec. 1, Aug. 15, 1985, 99 Stat. 387, provided that: "This Act (amending sections 360aa to 360cc, and 360ee of

this title, and sections 295g−1 and 6022 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under section 360aa of this title and section 236 of Title 42) may be cited as the 'Orphan Drug Amendments of 1985'."

SHORT TITLE OF 1984 AMENDMENT

Pub. L. 98−417, Sec. 1, Sept. 24, 1984, 98 Stat. 1585, provided: "That this Act (enacting section 156 of Title 35, Patents, amending sections 355 and 360cc of this title, sections 68b, 68c, and 70b of Title 15, Commerce and Trade, section 2201 of Title 28, Judiciary and Judicial Procedure, and sections 271 and 282 of Title 35, and enacting provisions set out as notes under section 355 of this title and section 68b of Title 15) may be cited as the 'Drug Price Competition and Patent Term Restoration Act of 1984'."

SHORT TITLE OF 1983 AMENDMENTS

Pub. L. 98−22, Sec. 1, Apr. 22, 1983, 97 Stat. 173, provided: "That this Act (amending provisions set out as a note under section 348 of this title) may be cited as the 'Saccharin Study and Labeling Act Amendment of 1983'."

Pub. L. 97−414, Sec. 1(a), Jan. 4, 1983, 96 Stat. 2049, provided that: "This Act (enacting part B of subchapter V of chapter 9 of this title, section 44H of Title 26, Internal Revenue Code, section 155 of Title 35, Patents, and sections 236, 255, and 298b−4 of Title 42, The Public Health and Welfare, amending sections 1274, 1472, 2055, 2060, 2064, 2068, and 2080 of Title 15, Commerce and Trade, section 904 of this title, sections 280C and 6096 of Title 26, and sections 209, 231, 242k, 242m, 243, 254c, 254j, 254m, 254o,

254p, 256, 294j, 295g−1, 295g−4, 295h, 295h−1a, 297−1, 300, 300a−1, 300a−3, 300b, 300e−1, 300m, 300n−5, 300q−2, 300u−5, 300w−3, 300x−1, 300x−4, 300y−11, 4577, and 4588 of Title 42, enacting provisions set out as notes under section 360aa of this title, section 44H of Title 26, and sections 241, 255, 287i, and 300x−1 of Title 42, and repealing provisions set out as a note under section 300t−11 of Title 42) may be cited as the 'Orphan Drug Act'."

SHORT TITLE OF 1981 AMENDMENT

Pub. L. 97−42, Sec. 1, Aug. 14, 1981, 95 Stat. 946, provided: "That this Act (amending provisions set out as a note under section 348 of this title) may be cited as the 'Saccharin Study and Labeling Act Amendment of 1981'."

SHORT TITLE OF 1980 AMENDMENT

Pub. L. 96−359, Sec. 1, Sept. 26, 1980, 94 Stat. 1190, provided: "That this Act (enacting section 350a of this title, amending sections 321, 331, 374, 830, 841 to 843, and 873 of this title, and enacting a provision set out as a note under section 350a of this title) may be cited as the 'Infant Formula Act of 1980'."

SHORT TITLE OF 1977 AMENDMENT

Pub. L. 95−203, Sec. 1, Nov. 23, 1977, 91 Stat. 1451, provided that: "This Act (enacting section 343a of this title, amending sections 321 and 343 of this title, enacting provisions set out as notes under sections 343 and 348 of this title, and amending provisions set out as notes under sections 218 and 289l−1 of Title 42, The Public Health and Welfare) may be cited as the 'Saccharin Study and Labeling Act'."

SHORT TITLE OF 1976 AMENDMENT

Pub. L. 94−295, Sec. 1(a), May 28, 1976, 90 Stat. 539, provided that: "This Act (enacting sections 360c to 360k, 379, and 379a of this title and section 3512 of Title 42, The Public Health and Welfare, and amending sections 321, 331, 334, 351, 352, 358, 360, 374, 379e, and 381 of this title and section 55 of Title 15, Commerce and Trade) may be cited as the 'Medical Device Amendments of 1976'."

SHORT TITLE OF 1972 AMENDMENT

Pub. L. 92−387, Sec. 1, Aug. 16, 1972, 86 Stat. 559, provided that: "This Act (amending sections 331, 335, and 360 of this title and enacting provisions set out as notes under section 360 of this title) may be cited as the 'Drug Listing Act of 1972'."

SHORT TITLE OF 1968 AMENDMENTS

Pub. L. 90−602, Sec. 1, Oct. 18, 1968, 82 Stat. 1173, provided that: "This Act (enacting provisions now comprising part C (Sec. 360hh−360ss) of subchapter III of this chapter and provisions set out as notes under section 360hh of this title) may be cited as the 'Radiation Control for Health and Safety Act of 1968'."

Pub. L. 90−399, Sec. 1, July 13, 1968, 82 Stat. 342, provided: "That this Act (enacting section 360b of this title, amending sections 321, 331, 342, 351, 352, 357, 381, and 392 of this title, and enacting provisions set out as a note under section 360b of this title) may be cited as the 'Animal Drug Amendments of 1968'."

SHORT TITLE OF 1965 AMENDMENT

Pub. L. 89−74, Sec. 1, July 15, 1965, 79 Stat. 226, provided:

"That this Act (amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321 and 352 of this title) may be cited as the 'Drug Abuse Control Amendments of 1965'."

SHORT TITLE OF 1962 AMENDMENT

Pub. L. 87−781, Sec. 1, Oct. 10, 1962, 76 Stat. 780, provided in part that such Act (enacting sections 358 to 360 of this title, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 358, 360, and 374 of this title) may be cited as the 'Drug Amendments of 1962'."

SHORT TITLE OF 1960 AMENDMENT

Pub. L. 86−618, Sec. 1, July 12, 1960, 74 Stat. 397, provided: "That this Act (amending sections 321, 331, 333, 342, 346, 351, 352, 361, 362, 371, and 379e of this title, repealing sections 354 and 364 of this title, and enacting notes set out under this section) may be cited as the 'Color Additive Amendments of 1960'."

SHORT TITLE OF 1958 AMENDMENT

Pub. L. 85−929, Sec. 1, Sept. 6, 1958, 72 Stat. 1784, provided: "That this Act (amending sections 321, 331, 342, 346, 348 of this title and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321, 342, and 451 of this title) may be cited as the 'Food Additives Amendment of 1958'."

−CITE−

21 USC SUBCHAPTER II − DEFINITIONS 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

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SUBCHAPTER II − DEFINITIONS

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21 USC Sec. 321 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

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Sec. 321. Definitions; generally

−STATUTE−

For the purposes of this chapter −

(a)(1) The term "State", except as used in the last sentence of section 372(a) of this title, means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between

any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food,

dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is −

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through

chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means −

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall

not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)(1)(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for

such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 348(h)(6) of this title, and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to

have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of −

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if −

(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this chapter other than sections 342(a)(2)(B) and 346a of this title.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common

use in food) to be safe under the conditions of its intended use;

except that such term does not include −

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended and extended (21 U.S.C. 601 et seq.);

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)(1) The term "color additive" means a material which −

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

(u) The term "safe" as used in paragraph (s) of this section and in sections 348, 360b, and 379e of this title, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, −

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a

result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(w) The term "animal feed", as used in paragraph (w) (FOOTNOTE 1) of this section, in section 360b of this title, and in provisions of this chapter referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(FOOTNOTE 1) So in original. Probably should be paragraph "(v)".

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of title 5 and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be

given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its

suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 355(j) of this title for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and −

(1) in the case of section 335a of this title, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 335b and 335c of this title, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information −

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 335a of this title, the term "high managerial agent" −

(1) means −

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for −

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 335a and 335b of this title, the term "drug product" means a drug subject to regulation under section 355, 360b, or 382 of this title or under section 262 of title 42.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement" −

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or

combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that −

(A)(i) is intended for ingestion in a form described in section 350(c)(1)(B)(i) of this title; or

(ii) complies with section 350(c)(1)(B)(ii) of this title;

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does −

(A) include an article that is approved as a new drug under section 355 of this title or licensed as a biologic under section 262 of title 42 and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 342(f) of this title; and

(B) not include −

(i) an article that is approved as a new drug under section 355 of this title, certified as an antibiotic under section 357 of this title, or licensed as a biologic under section 262 of title 42, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical

investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this chapter.

Except for purposes of paragraph (g), a dietary supplement shall be deemed to be a food within the meaning of this chapter.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug" −

(1) means a drug that −

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro−organism and which has the capacity to inhibit or destroy micro−organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) Priority supplement. − The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)(1) The term "single−use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)(A) The term "reprocessed", with respect to a single−use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single−use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single−use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single−use device.

(mm)(1) The term "critical reprocessed single−use device" means a reprocessed single−use device that is intended to contact normally sterile tissue or body spaces during use.

(2) The term "semi−critical reprocessed single−use device" means a reprocessed single−use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 201, 52 Stat. 1040; July 22, 1954, ch. 559, Sec. 1, 68 Stat. 511; Pub. L. 85−929, Sec. 2, Sept. 6, 1958, 72 Stat. 1784; Pub. L. 86−618, title I, Sec. 101, July 12, 1960, 74 Stat. 397; Pub. L. 87−781, title I, Sec. 102(a), title III, Sec. 307(a), Oct. 10, 1962, 76 Stat. 781, 796; Pub. L. 89−74, Sec. 3(a), 9(b), July 15, 1965, 79 Stat. 227, 234; Pub. L. 90−399, Sec. 102, July 13, 1968, 82 Stat. 351; Pub. L. 90−639, Sec. 1, 4(a), Oct. 24, 1968, 82 Stat. 1361, 1362; Pub. L. 91−513, title II, Sec. 701(a), (g), Oct. 27, 1970, 84 Stat. 1281, 1282; Pub. L. 92−516, Sec. 3(3), Oct. 21, 1972, 86 Stat. 998; Pub. L. 94−278, title V, Sec. 502(a)(2)(A), Apr. 22, 1976, 90 Stat. 411; Pub. L.

94−295, Sec. 3(a)(1)(A), (2), May 28, 1976, 90 Stat. 575; Pub. L. 95−203, Sec. 4(b)(3), Nov. 23, 1977, 91 Stat. 1453; Pub. L. 96−359, Sec. 3, Sept. 26, 1980, 94 Stat. 1193; Pub. L. 100−670, title I, Sec. 107(a)(1), Nov. 16, 1988, 102 Stat. 3984; Pub. L. 101−535, Sec. 5(b), Nov. 8, 1990, 104 Stat. 2362; Pub. L. 101−629, Sec. 16(b), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 102−282, Sec. 6, May 13, 1992, 106 Stat. 161; Pub. L. 102−300, Sec. 6(a), (b), June 16, 1992, 106 Stat. 240; Pub. L. 102−571, title I, Sec. 107(1), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103−80, Sec. 3(b), (dd)(1), 4(b), Aug. 13, 1993, 107 Stat. 775, 779; Pub. L. 103−417, Sec. 3(a), (b), 10(a), Oct. 25, 1994, 108 Stat. 4327, 4332; Pub. L. 104−170, title IV, Sec. 402, Aug. 3, 1996, 110 Stat. 1513; Pub. L. 105−115, title I, Sec. 121(a), 125(b)(2)(A), (e), Nov. 21, 1997, 111 Stat. 2320, 2325, 2327; Pub. L. 105−324, Sec. 2(a), (c), Oct. 30, 1998, 112 Stat. 3035, 3037; Pub. L. 107−109, Sec. 5(b)(1), Jan. 4, 2002, 115 Stat. 1413; Pub. L. 107−250, title III, Sec. 302(d), Oct. 26, 2002, 116 Stat. 1619.)

−REFTEXT−

REFERENCES IN TEXT

The Food and Drugs Act of June 30, 1906, as amended, referred to in par. (p)(1), and the Food and Drug Act of June 30, 1906, as amended, referred to in par. (v)(1), is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (Sec. 1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 372a of this title) by act June 25, 1938, ch. 675, Sec. 902(a), 52 Stat. 1059,

and is covered by this chapter.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in par. (q)(1), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92−516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (Sec. 136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Poultry Products Inspection Act, referred to in par. (s)(4), is Pub. L. 85−172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (Sec. 451 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 451 of this title and Tables.

The Meat Inspection Act of March 4, 1907, as amended and extended, referred to in par. (s)(4), is act Mar. 4, 1907, ch. 2907, titles I to IV, as added Dec. 15, 1967, Pub. L. 90−201, 81 Stat. 584, which are classified generally to subchapters I to IV (Sec. 601 et seq.) of chapter 12 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 601 of this title and Tables.

Section 101(4) of the Food and Drug Administration Modernization Act of 1997, referred to in par. (kk), is section 101(4) of Pub. L. 105−115, which is set out as a note under section 379g of this title.

AMENDMENTS

2002 − Pars. (ll), (mm). Pub. L. 107−250 added pars. (ll) and (mm).

Par. (kk). Pub. L. 107−109 added par. (kk).

1998 − Par. (q)(1). Pub. L. 105−324, Sec. 2(a), added subpar. (1) and struck out former subpar. (1) which read as follows: "The term 'pesticide chemical' means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide."

Par. (q)(3). Pub. L. 105−324, Sec. 2(c), substituted "subparagraphs (1) and (2)" for "paragraphs (1) and (2)" in introductory provisions.

1997 − Par. (aa). Pub. L. 105−115, Sec. 125(b)(2)(A), struck out "or 357" after "section 355(j)".

Par. (dd). Pub. L. 105−115, Sec. 125(b)(2)(A), struck out "357," after "section 355,".

Par. (ff)(3)(A). Pub. L. 105−115, Sec. 125(b)(2)(A), struck out ", certified as an antibiotic under section 357 of this title," before "or licensed as a biologic".

Par. (ii). Pub. L. 105−115, Sec. 121(a), added par. (ii).

Par. (jj). Pub. L. 105−115, Sec. 125(e), added par. (jj).

1996 − Par. (q). Pub. L. 104−170, Sec. 402(a), amended par. (q) generally. Prior to amendment, par. (q) read as follows: "The term 'pesticide chemical' means any substance which, alone, in chemical combination or in formulation with one or more other

substances, is 'a pesticide' within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities."

Par. (s)(1), (2). Pub. L. 104−170, Sec. 402(b), amended subpars. (1) and (2) generally. Prior to amendment, subpars. (1) and (2) read as follows:

"(1) a pesticide chemical in or on a raw agricultural commodity; or

"(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or".

Pars. (gg), (hh). Pub. L. 104−170, Sec. 402(c), added pars. (gg) and (hh).

1994 − Par. (g)(1). Pub. L. 103−417, Sec. 10(a), amended last sentence generally. Prior to amendment, last sentence read as follows: "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."

Par. (s)(6). Pub. L. 103−417, Sec. 3(b), added subpar. (6).

Par. (ff). Pub. L. 103−417, Sec. 3(a), added par. (ff).

1993 − Pars. (c), (d). Pub. L. 103−80, Sec. 3(dd)(1), substituted "Health and Human Services" for "Agriculture".

Par. (h). Pub. L. 103−80, Sec. 4(b), amended directory language of Pub. L. 102−300, Sec. 6(a)(1). See 1992 amendment note below.

Pars. (v) to (ff). Pub. L. 103−80, Sec. 3(b), redesignated pars. (w) to (ff) as (v) to (ee), respectively.

1992 − Pars. (c), (d). Pub. L. 102−300, Sec. 6(b)(1), which directed the substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions notes below.

Par. (h). Pub. L. 102−300, Sec. 6(a)(1), as amended by Pub. L. 103−80, Sec. 4(b), substituted "its primary" for "any of its principal" in two places in concluding provisions.

Par. (u). Pub. L. 102−571 substituted "379e" for "376".

Par. (y)(1). Pub. L. 102−300, Sec. 6(b)(2), struck out "of Health, Education, and Welfare" after "employees of the Department".

Pars. (bb) to (ee). Pub. L. 102−282 added pars. (bb) to (ee).

Par. (ff). Pub. L. 102−300, Sec. 6(a)(2), added par. (ff).

1990 − Par. (g)(1). Pub. L. 101−629, Sec. 16(b)(1), struck out "; but does not include devices or their components, parts, or accessories" after "clause (A), (B), or (C)".

Pub. L. 101−535 inserted at end "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling

contains such a claim."

Par. (h)(3). Pub. L. 101−629, Sec. 16(b)(2), which directed the amendment of subpar. (3) by substituting "its primary" for "any of its principal", could not be executed because "any of its principal" did not appear in subpar. (3).

1988 − Par. (w)(3). Pub. L. 100−670 struck out subpar. (3) which read as follows: "which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 360b(n) of this title, is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug."

1980 − Par. (aa). Pub. L. 96−359 added par. (aa).

1977 − Par. (z). Pub. L. 95−203 added par. (z).

1976 − Par. (h). Pub. L. 94−295, Sec. 3(a)(1)(A), expanded definition of "device" to include implements, machines, implants, in vitro reagents, and other similar or related articles, added recognition in the National Formulary or the United States Pharmacopeia, or any supplement to the Formulary or Pharmacopeia, to the enumeration of conditions under which a device may qualify for inclusion under this chapter, and inserted requirements that a device be one which does not achieve any of its principal intended

purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Par. (n). Pub. L. 94−278 inserted "or advertising" after "labeling" wherever appearing.

Par. (y). Pub. L. 94−295, Sec. 3(a)(2), added par. (y).

1972 − Par. (q). Pub. L. 92−516 substituted reference to pesticide for reference to economic poison.

1970 − Par. (a)(2). Pub. L. 91−513, Sec. 701(g), struck out reference to sections 321, 331(i), 331(p), 331(q), 332, 333, 334, 337, 360, 360a, 372, 373, 374, and 375 of this title as they apply to depressant or stimulant drugs.

Par. (v). Pub. L. 91−513, Sec. 701(a), struck out par. (v) which defined "depressant or stimulant drug".

1968 − Par. (a)(2). Pub. L. 90−639, Sec. 4(a), extended provisions to cover depressant and stimulant drugs, the containers thereof, and equipment used in manufacturing, compounding, or processing such drugs, to the Canal Zone.

Par. (p). Pub. L. 90−399, Sec. 102(a), (b), inserted "(except a new animal drug or an animal feed bearing or containing a new animal drug)" after "Any drug" in subpars. (1) and (2), respectively.

Par. (s)(5). Pub. L. 90−399, Sec. 102(c), added subpar. (5).

Par. (u). Pub. L. 90−399, Sec. 102(d), inserted reference to section 360b of this title.

Par. (v)(3). Pub. L. 90−639, Sec. 1, inserted reference to

lysergic acid diethylamide.

Pars. (w), (x). Pub. L. 90−399, Sec. 102(e), added pars. (w) and (x).

1965 − Par. (g). Pub. L. 89−74, Sec. 9(b), designated existing provisions as subpar. (1), redesignated cls. (1) to (4) thereof as (A) to (D), substituted "(A), (B), or (C)" for "(1), (2), or (3)" and added subpar. (2).

Par. (v). Pub. L. 89−74, Sec. 3(a), added par. (v).

1962 − Par. (a). Pub. L. 87−781, Sec. 307(a), designated existing provisions as subpar. (2), inserted "Commonwealth of Puerto Rico and the", and added subpar. (1).

Par. (p)(1). Pub. L. 87−781, Sec. 102(a)(1), inserted "and effectiveness" after "to evaluate the safety", and "and effective" after "as safe".

Par. (p)(2). Pub. L. 87−781, Sec. 102(a)(2), inserted "and effectiveness" after "safety".

1960 − Par. (s). Pub. L. 86−618, Sec. 101(a), excluded color additives from definition of "food additive".

Par. (t). Pub. L. 86−618, Sec. 101(c), added par. (t). Former par. (t) redesignated (u).

Par. (u). Pub. L. 86−618, Sec. 101(b), redesignated par. (t) as (u) and inserted reference to section 376 of this title.

1958 − Pars. (s), (t). Pub. L. 85−929 added pars. (s) and (t).

1954 − Pars. (q), (r). Act July 22, 1954, added pars. (q) and (r).

EFFECTIVE DATE OF 1997 AMENDMENT

Section 501 of Pub. L. 105−115 provided that: "Except as otherwise provided in this Act (see Short Title of 1997 Amendment note set out under section 301 of this title), this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307 (enacting section 355a of this title, amending this section and sections 331, 335a, 351, 352, 360, 360j, 360aa to 360cc, 360ee, 374, 379g, 381, and 382 of this title, section 45C of Title 26, Internal Revenue Code, section 156 of Title 35, Patents, and section 8126 of Title 38, Veterans' Benefits, repealing sections 356 and 357 of this title, and enacting provisions set out as notes under sections 351 and 355 of this title), shall take effect 90 days after the date of enactment of this Act (Nov. 21, 1997)."

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101−535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations (Nov. 8, 1992), with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101−535, set out as a note under section 343 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94−278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94−278, set out as a note under

section 334 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92−516 effective at the close of Oct. 21, 1972, except if regulations are necessary for the implementation of any provision that becomes effective on Oct. 21, 1972, and continuation in effect of subchapter I of chapter 6 of Title 7, and regulations thereunder, relating to the control of economic poisons, as in existence prior to Oct. 21, 1972, until superseded by provisions of Pub. L. 92−516, and regulations thereunder, see section 4 of Pub. L. 92−516, set out as an Effective Date note under section 136 of Title 7, Agriculture.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91−513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91−513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS; TRANSITIONAL PROVISIONS

Section 6 of Pub. L. 90−639 provided that: "The amendments made by this Act (amending this section, sections 331, 333, 334, and 360a of this title, and provisions set out as a note under section 289a of Title 42, The Public Health and Welfare) shall apply only with respect to violations of the Federal Food, Drug, and Cosmetic Act (this chapter) committed after the date of the enactment of this Act (Oct. 24, 1968)."

Amendment by Pub. L. 90−399 effective on first day of thirteenth calendar month after July 13, 1968, except that in the case of a

drug (other than one subject to section 360b(n) of this title) intended for use in animals other than man which, on Oct. 9, 1962, was commercially used or sold in the United States, was not a new drug as defined in par. (p) of this section then in force, and was not covered by an effective application under section 355 of this title, the words "effectiveness" and "effective" contained in par. (w) of this section not applicable to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day, see section 108(a), (b)(3) of Pub. L. 90−399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Section 11 of Pub. L. 89−74 provided that: "The foregoing provisions of this Act (see Short Title of 1965 Amendment note set out under section 301 of this title) shall take effect on the first day of the seventh calendar month (Feb. 1, 1966) following the month in which this Act is enacted (July 15, 1965); except that (1) the Secretary shall permit persons, owning or operating any establishment engaged in manufacturing, preparing, propagating, compounding, processing, wholesaling, jobbing, or distributing any depressant or stimulant drug, as referred to in the amendments made by section 4 of this Act to section 510 of the Federal Food, Drug, and Cosmetic Act (section 360 of this title), to register their name, places of business, and establishments, and other information prescribed by such amendments, with the Secretary prior to such

effective date, and (2) sections 201(v) and 511(g) of the Federal Food, Drug, and Cosmetic Act, as added by this act (par. (v) of this section and par. (g) of section 360a of this title), and the provisions of sections 8 (amending section 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure) and 10 (set out as a note under this section) shall take effect upon the date of enactment of this Act (July 15, 1965)."

EFFECTIVE DATE OF 1962 AMENDMENT

Section 107 of Pub. L. 87−781 provided that:

"(a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A (amending this section and sections 331, 332, 348, 351 to 353, 355, 357, 379e of this title, and enacting provisions set out as a note under section 355 of this title) shall take effect on the date of enactment of this Act (Oct. 10, 1962).

"(b) The amendments made by sections 101, 103, 105, and 106 of this part A (amending sections 331, 332, 351, 352, 355, and 357 of this title) shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted (Oct. 1962).

"(c)(1) As used in this subsection, the term 'enactment date' means the date of enactment of this Act; and the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act (this chapter).

"(2) An application filed pursuant to section 505(b) of the basic Act (section 355(b) of this title) which was 'effective' within the meaning of that Act on the day immediately preceding the

enactment date shall be deemed as of the enactment date, to be an application 'approved' by the Secretary within the meaning of the basic Act as amended by this Act.

"(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection −

"(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act (par. (p) of this section, and subsecs. (b) and (d) of section 355 of this title), insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act (section 355(e) of this title), apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

"(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act (section 355(e) of this title), shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such

use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act (section 355 of this title)) until whichever of the following first occurs:
(i) the expiration of the two−year period beginning with the enactment date; (ii) the effective date of an order under section 505(e) of the basic Act (section 355(e) of this title), other than clause (3) of the first sentence of such section 505(e) (section 355(e) of this title), withdrawing or suspending the approval of such application.
"(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force (par. (p) of this section), and (C) was not covered by an effective application under section 505 of that Act (section 355 of this title), the amendments to section 201(p) (par. (p) of this section) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."
EFFECTIVE DATE OF 1960 AMENDMENT
Amendment by Pub. L. 86−618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86−618, see section 202 of Pub. L. 86−618, set out as a note under section 379e of this title.
EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85−929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85−929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1954 AMENDMENT

For effective date of amendment by act July 22, 1954, see section 5 of that act, set out as a note under section 342 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 102−282

Amendment by Pub. L. 102−282 not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102−282, see section 7 of Pub. L. 102−282, set out as a note under section 335a of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101−535

Amendments by Pub. L. 101−535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101−535, set out as a note under section 343 of this title.

SAVINGS PROVISION

Section 702 of Pub. L. 91−513, as amended by Pub. L. 93−481, Sec. 2, Oct. 26, 1974, 88 Stat. 1455, provided that:

"(a) Prosecutions for any violation of law occurring prior to

the effective date (see Effective Date of 1970 Amendment note above) of section 701 (repealing section 360a of this title, and amending sections 321, 331, 333, 334, 360, 372, and 381 of this title, sections 1114 and 1952 of Title 18, Crimes and Criminal Procedure, and section 242 of Title 42, The Public Health and Welfare) shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(b) Civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of section 701 shall not be affected by the repeals or amendments made by such section, or abated by reason thereof.

"(c) All administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) on the date of enactment of this Act (Oct. 27, 1970) shall be continued and brought to final determination in accord with laws and regulations in effect prior to such date of enactment. Where a drug is finally determined under such proceedings to be a depressant or stimulant drug, as defined in section 201(v) of the Federal Food, Drug, and Cosmetic Act (par. (v) of this section), such drug shall automatically be controlled under this title (subchapter I of chapter 13 of this title) by the Attorney General without further proceedings and listed in the appropriate schedule after he has obtained the recommendation of the Secretary. Any drug with respect to which such a final determination has been made prior to the date of enactment of this Act which is not listed in section 202 (section 812 of this title)

within schedules I through V shall automatically be controlled under this title (subchapter I of chapter 13 of this title) by the Attorney General without further proceedings, and be listed in the appropriate schedule, after he has obtained the recommendations of the Secretary.

"(d) Notwithstanding subsection (a) of this section or section 1103 (of Pub. L. 91−513, set out as a note under sections 171 to 174 of this title), section 4202 of title 18, United States Code, shall apply to any individual convicted under any of the laws repealed by this title or title III (subchapter I or subchapter II of chapter 13 of this title) without regard to the terms of any sentence imposed on such individual under such law."

−TRANS−

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96−88, title V, Sec. 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

Functions of Secretary of Health, Education, and Welfare (now Health and Human Services) under Federal Food, Drug, and Cosmetic Act, to the extent such functions related to administration and enforcement of the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), transferred to Consumer Product Safety Commission by section 2079 of Title 15, Commerce and Trade.

Functions of Secretary of Health, Education, and Welfare (now Health and Human Services) under Drug Abuse Control Amendments of

1965 (see Short Title of 1965 Amendment note set out under section 301 of this title) transferred to Attorney General except function of regulating counterfeiting of those drugs which are not "depressant or stimulant" drugs, see section 2 of Reorg. Plan No. 1 of 1968, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−MISC5−

REGULATION OF TOBACCO

Section 422 of Pub. L. 105−115 provided that: "Nothing in this Act (see Short Title of 1997 Amendment note set out under section 301 of this title) or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) as in effect on the day before the date of the enactment of this Act (Nov. 21, 1997)."

CONGRESSIONAL FINDINGS RELATING TO PUB. L. 103−417

Section 2 of Pub. L. 103−417 provided that: "Congress finds that

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"(1) improving the health status of United States citizens

ranks at the top of the national priorities of the Federal Government;

"(2) the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention have been documented increasingly in scientific studies;

"(3)(A) there is a link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and

"(B) clinical research has shown that several chronic diseases can be prevented simply with a healthful diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant−based foods;

"(4) healthful diets may mitigate the need for expensive medical procedures, such as coronary bypass surgery or angioplasty;

"(5) preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long−term health care expenditures;

"(6)(A) promotion of good health and healthy lifestyles improves and extends lives while reducing health care expenditures; and

"(B) reduction in health care expenditures is of paramount importance to the future of the country and the economic well−being of the country;

"(7) there is a growing need for emphasis on the dissemination

of information linking nutrition and long−term good health;

"(8) consumers should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements;

"(9) national surveys have revealed that almost 50 percent of the 260,000,000 Americans regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition;

"(10) studies indicate that consumers are placing increased reliance on the use of nontraditional health care providers to avoid the excessive costs of traditional medical services and to obtain more holistic consideration of their needs;

"(11) the United States will spend over $1,000,000,000,000 on health care in 1994, which is about 12 percent of the Gross National Product of the United States, and this amount and percentage will continue to increase unless significant efforts are undertaken to reverse the increase;

"(12)(A) the nutritional supplement industry is an integral part of the economy of the United States;

"(B) the industry consistently projects a positive trade balance; and

"(C) the estimated 600 dietary supplement manufacturers in the United States produce approximately 4,000 products, with total annual sales of such products alone reaching at least $4,000,000,000;

"(13) although the Federal Government should take swift action against products that are unsafe or adulterated, the Federal Government should not take any actions to impose unreasonable regulatory barriers limiting or slowing the flow of safe products and accurate information to consumers;

"(14) dietary supplements are safe within a broad range of intake, and safety problems with the supplements are relatively rare; and

"(15)(A) legislative action that protects the right of access of consumers to safe dietary supplements is necessary in order to promote wellness; and

"(B) a rational Federal framework must be established to supersede the current ad hoc, patchwork regulatory policy on dietary supplements."

DISSEMINATION OF INFORMATION REGARDING THE DANGERS OF DRUG ABUSE

Section 5 of Pub. L. 90−639 provided that: "It is the sense of the Congress that, because of the inadequate knowledge on the part of the people of the United States of the substantial adverse effects of misuse of depressant and stimulant drugs, and of other drugs liable to abuse, on the individual, his family, and the community, the highest priority should be given to Federal programs to disseminate information which may be used to educate the public, particularly young persons, regarding the dangers of drug abuse."

CONGRESSIONAL FINDINGS AND DECLARATION OF POLICY

Section 2 of Pub. L. 89−74 provided that: "The Congress hereby finds and declares that there is a widespread illicit traffic in

depressant and stimulant drugs moving in or otherwise affecting interstate commerce; that the use of such drugs, when not under the supervision of a licensed practitioner, often endangers safety on the highways (without distinction of interstate and intrastate traffic thereon) and otherwise has become a threat to the public health and safety, making additional regulation of such drugs necessary regardless of the intrastate or interstate origin of such drugs; that in order to make regulation and protection of interstate commerce in such drugs effective, regulation of intrastate commerce is also necessary because, among other things, such drugs, when held for illicit sale, often do not bear labeling showing their place of origin and because in the form in which they are so held or in which they are consumed a determination of their place of origin is often extremely difficult or impossible; and that regulation of interstate commerce without the regulation of intrastate commerce in such drugs, as provided in this Act (see Short Title of 1965 Amendment note set out under section 301 of this title), would discriminate against and adversely affect interstate commerce in such drugs."

EFFECT OF DRUG ABUSE CONTROL AMENDMENTS OF 1965 ON STATE LAWS

Section 10 of Pub. L. 89−74 provided that:

"(a) Nothing in this Act (enacting section 360a of this title, amending sections 321, 331, 333, 334, 360, and 372 of this title and section 1114 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under sections 321, 352, and 360a of this title) shall be construed as authorizing the

manufacture, compounding, processing, possession, sale, delivery, or other disposal of any drug in any State in contravention of the laws of such State.

"(b) No provision of this Act nor any amendment made by it shall be construed as indicating an intent on the part of the Congress to occupy the field in which such provision or amendment operates to the exclusion of any State law on the same subject matter, unless there is a direct and positive conflict between such provision or amendment and such State law so that the two cannot be reconciled or consistently stand together.

"(c) No amendment made by this Act shall be construed to prevent the enforcement in the courts of any State of any statute of such State prescribing any criminal penalty for any act made criminal by any such amendment."

EFFECT OF DRUG AMENDMENTS OF 1962 ON STATE LAWS

Section 202 of Pub. L. 87−781 provided that: "Nothing in the amendments made by this Act (enacting sections 358 to 360, amending sections 321, 331, 332, 348, 351 to 353, 355, 357, 372, 374, 379e, and 381 of this title, and enacting provisions set out as notes under sections 321, 331, 332, 352, 355, 360, and 374 of this title) to the Federal Food, Drug, and Cosmetic Act (this chapter) shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."

−CROSS−

DEFINITIONS

Section 2 of Pub. L. 105−115 provided that: "In this Act (see Short Title of 1997 Amendment note set out under section 301 of this title), the terms 'drug', 'device', 'food', and 'dietary supplement' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)."

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 343, 343−3, 346a, 346b, 350, 352, 353a, 355, 360b, 379e, 383, 802, 825, 1602 of this title; title 7 section 136; title 15 sections 1454, 1456, 1471, 2052, 2602; title 18 section 1365; title 22 section 7201; title 35 section 156; title 42 sections 274e, 287c−11, 289g−2, 300cc−12, 1396r−8; title 49 section 5702.

−CITE−

21 USC Sec. 321a 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

−HEAD−

Sec. 321a. "Butter" defined

−STATUTE−

For the purposes of the Food and Drug Act of June 30, 1906 (Thirty−fourth Statutes at Large, page 768) "butter" shall be understood to mean the food product usually known as butter, and

which is made exclusively from milk or cream, or both, with or without common salt, and with or without additional coloring matter, and containing not less than 80 per centum by weight of milk fat, all tolerances having been allowed for.

−SOURCE−

(Mar. 4, 1923, ch. 268, 42 Stat. 1500.)

−REFTEXT−

REFERENCES IN TEXT

The Food and Drug Act of June 30, 1906, referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, as amended, which was classified to subchapter I (Sec. 1 et seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, Sec. 902(a), 52 Stat. 1059, and is covered by this chapter.

−COD−

CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to section 6 of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

−CITE−

21 USC Sec. 321b 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

−HEAD−

Sec. 321b. "Package" defined

−STATUTE−

The word "package" where it occurs the second and last time in the act entitled "An act to amend section 8 of an act entitled, 'An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,' " approved March 3, 1913, shall include and shall be construed to include wrapped meats inclosed in papers or other materials as prepared by the manufacturers thereof for sale.

−SOURCE−

(July 24, 1919, ch. 26, 41 Stat. 271.)

−REFTEXT−

REFERENCES IN TEXT

An act approved March 3, 1913, referred to in text, is act Mar. 3, 1913, ch. 117, 37 Stat. 732, which amended section 10 of this title. For complete classification of this Act to the Code, see Tables.

"An act for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes,", referred to in text, is act June 30, 1906, ch. 3915, 34 Stat. 768, which was classified to subchapter I (Sec. 1 et

seq.) of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, Sec. 902(a), 52 Stat. 1059, and is covered by this chapter.

−COD−

CODIFICATION

Section, which was not enacted as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, was formerly classified to the last sentence of paragraph third of section 10 of this title. Section 902(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that this section should remain in force and effect and be applicable to the provisions of this chapter.

−CITE−

21 USC Sec. 321c 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

−HEAD−

Sec. 321c. Nonfat dry milk; "milk" defined

−STATUTE−

For the purposes of the Federal Food, Drug, and Cosmetic Act of June 26, 1938, (ch. 675, sec. 1, 52 Stat. 1040) (21 U.S.C. 301 et seq.) nonfat dry milk is the product resulting from the removal of fat and water from milk, and contains the lactose, milk proteins,

and milk minerals in the same relative proportions as in the fresh milk from which made. It contains not over 5 per centum by weight of moisture. The fat content is not over 1 1/2 per centum by weight unless otherwise indicated.

The term "milk", when used herein, means sweet milk of cows.

−SOURCE−

(Mar. 2, 1944, ch. 77, 58 Stat. 108; July 2, 1956, ch. 495, 70 Stat. 486.)

−REFTEXT−

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act of June 26, 1938 (ch. 675, sec. 1, 52 Stat. 1040), referred to in text, probably means act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter (Sec. 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

−COD−

CODIFICATION

Section was not enacted as a part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter, but was made applicable thereto.

−MISC3−

AMENDMENTS

1956 − Act July 2, 1956, substituted "nonfat dry milk" for "nonfat dry milk solids or defatted milk solids".

−CITE−

21 USC Sec. 321d 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER II − DEFINITIONS

−HEAD−

Sec. 321d. Market names for catfish and ginseng

−STATUTE−

(a) Catfish labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) −

(A) the term "catfish" may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and

(B) only labeling or advertising for fish classified within that family may include the term "catfish".

(2) Omitted

(b) Ginseng labeling

(1) In general

Notwithstanding any other provision of law, for purposes of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) −

(A) the term "ginseng" may only be considered to be a common or usual name (or part thereof) for any herb or herbal ingredient derived from a plant classified within the genus Panax; and

(B) only labeling or advertising for herbs or herbal ingredients classified within that genus may include the term "ginseng".

(2) Omitted

−SOURCE−

(Pub. L. 107−171, title X, Sec. 10806, May 13, 2002, 116 Stat. 526.)

−REFTEXT−

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(1), (b)(1), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

−COD−

CODIFICATION

Section is comprised of section 10806 of Pub. L. 107−171.

Subsecs. (a)(2) and (b)(2) of section 10806 of Pub. L. 107−171 amended section 343 of this title.

Section was enacted as part of the Farm Security and Rural Investment Act of 2002, and not as part of Federal Food, Drug, and Cosmetic Act which comprises this chapter.

−CITE−

21 USC SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

.

−HEAD−

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−SECREF−

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in sections 343, 378 of this

title; title 15 section 1456.

−CITE−

21 USC Sec. 331 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 331. Prohibited acts

−STATUTE−

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate

commerce of any food, drug, device, or cosmetic that is adulterated

or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or

cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device,

or cosmetic that is adulterated or misbranded, and the delivery or

proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 354, 373, or 374(a) of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (l), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.

(f) The refusal to permit entry or inspection as authorized by section 374 of this title.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 333(c)(2) of this title, which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c)(3) of this title, which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required

by regulations promulgated under the provisions of section 344 or 379e of this title.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 350c, 355, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 379, or 379e of this title concerning any method or process which as a trade secret is entitled to protection; or the violating of section 346a(i)(2) of this title or any regulation issued under that section.. (FOOTNOTE 1) This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(FOOTNOTE 1) So in original.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) Repealed. Pub. L. 105−115, title IV, Sec. 421, Nov. 21, 1997, 111 Stat. 2380.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 374 of this title.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to

exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

(p) The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) or 360(k) of this title, or the failure to provide a notice required by section 360(j)(2) of this title.

(q)(1) The failure or refusal to (A) comply with any requirement prescribed under section 360h or 360j(g) of this title, (B) furnish any notification or other material or information required by or under section 360i or 360j(g) of this title, or (C) comply with a requirement under section 360l of this title.

(2) With respect to any device, the submission of any report that is required by or under this chapter that is false or misleading in any material respect.

(r) The movement of a device in violation of an order under section 334(g) of this title or the removal or alteration of any mark or label required by the order to identify the device as detained.

(s) The failure to provide the notice required by section 350a(c) or 350a(e) of this title, the failure to make the reports required by section 350a(f)(1)(B) of this title, the failure to retain the records required by section 350a(b)(4) of this title, or the failure to meet the requirements prescribed under section 350a(f)(3) of this title.

(t) The importation of a drug in violation of section 381(d)(1) of this title, the sale, purchase, or trade of a drug or drug

sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, the distribution of a drug sample in violation of section 353(d) of this title or the failure to otherwise comply with the requirements of section 353(d) of this title, or the distribution of drugs in violation of section 353(e) of this title or the failure to otherwise comply with the requirements of section 353(e) of this title.

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 360b(a)(4)(A), 360b(a)(4)(D), or 360b(a)(5) of this title.

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 381(d)(3) of this title; the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 381(e) or 382 of this title, or with section 262(h) of title 42; or the failure to so

export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 360d(c) of this title or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food −

(1) the submission of a report or recommendation by a person accredited under section 360m of this title that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 360m of this title of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 360m of this title of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this chapter.

(z) The dissemination of information in violation of section 360aaa of this title.

(aa) The importation of a covered product in violation of section 384 of this title, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 334(h) of this title, or the removal or alteration of

any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 335a(b)(3) of this title.

(dd) The failure to register in accordance with section 350d of this title.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 381(m) of this title.

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 381(o) of this title.

(gg) The knowing failure of a person accredited under paragraph (2) of section 374(g) of this title to comply with paragraph (7)(E) of such section; the knowing inclusion by such a person of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 301, 52 Stat. 1042; Dec. 22, 1941, ch. 613, Sec. 1, 55 Stat. 851; July 6, 1945, ch. 281, Sec. 1, 59 Stat. 463; Mar. 10, 1947, ch. 16, Sec. 1, 61 Stat. 11; June 24, 1948, ch. 613, Sec. 1, 62 Stat. 582; Mar. 16, 1950, ch. 61, Sec.

3(b), 64 Stat. 20; Aug. 7, 1953, ch. 350, Sec. 2, 67 Stat. 477;

Pub. L. 85−929, Sec. 5, Sept. 6, 1958, 72 Stat. 1788; Pub. L.

86−618, title I, Sec. 104, 105(a), July 12, 1960, 74 Stat. 403;

Pub. L. 87−781, title I, Sec. 103(c), 104(e)(1), 106(c), 114(a),

title III, Sec. 304, Oct. 10, 1962, 76 Stat. 784, 785, 788, 791,

795; Pub. L. 89−74, Sec. 5, 9(c), July 15, 1965, 79 Stat. 232, 235;

Pub. L. 90−399, Sec. 103, July 13, 1968, 82 Stat. 352; Pub. L.

90−639, Sec. 2(b), Oct. 24, 1968, 82 Stat. 1361; Pub. L. 91−513,

title II, Sec. 701(a), Oct. 27, 1970, 84 Stat. 1281; Pub. L.

92−387, Sec. 4(e), Aug. 16, 1972, 86 Stat. 562; Pub. L. 94−295,

Sec. 3(b), 4(b)(1), 7(b), May 28, 1976, 90 Stat. 576, 580, 582;

Pub. L. 96−359, Sec. 5, Sept. 26, 1980, 94 Stat. 1193; Pub. L.

99−570, title IV, Sec. 4014(b)(2), Oct. 27, 1986, 100 Stat.

3207−120; Pub. L. 100−293, Sec. 7(a), Apr. 22, 1988, 102 Stat. 99;

Pub. L. 101−502, Sec. 5(j), Nov. 3, 1990, 104 Stat. 1289; Pub. L.

101−508, title IV, Sec. 4755(c)(2), Nov. 5, 1990, 104 Stat.

1388−210; Pub. L. 102−300, Sec. 3(a)(1), June 16, 1992, 106 Stat.

238; Pub. L. 102−571, title I, Sec. 107(2), (3), Oct. 29, 1992, 106

Stat. 4499; Pub. L. 103−80, Sec. 3(c), Aug. 13, 1993, 107 Stat.

775; Pub. L. 103−396, Sec. 2(b)(1), Oct. 22, 1994, 108 Stat. 4154;

Pub. L. 103−417, Sec. 10(b), Oct. 25, 1994, 108 Stat. 4332; Pub. L.

104−134, title II, Sec. 2103, Apr. 26, 1996, 110 Stat. 1321−319;

Pub. L. 104−170, title IV, Sec. 403, Aug. 3, 1996, 110 Stat. 1514;

Pub. L. 104−250, Sec. 5(d), Oct. 9, 1996, 110 Stat. 3156; Pub. L.

105−115, title I, Sec. 125(a)(2)(A), (C), (b)(2)(B), title II, Sec.

204(b), 210(c), title IV, Sec. 401(b), 421, Nov. 21, 1997, 111

Stat. 2325, 2336, 2345, 2364, 2380; Pub. L. 106−387, Sec. 1(a) (title VII, Sec. 745(d)(1)), Oct. 28, 2000, 114 Stat. 1549, 1549A−39; Pub. L. 107−188, title III, Sec. 303(b), 304(d), 305(b), 306(c), 307(b), 321(b)(2), 322(b), June 12, 2002, 116 Stat. 664, 666, 668, 670, 672, 676, 677; Pub. L. 107−250, title II, Sec. 201(d), Oct. 26, 2002, 116 Stat. 1609.)

−STATAMEND−

AMENDMENT OF SECTION

For termination of amendment by section 401(e) of Pub. L. 105−115, see Effective and Termination Dates of 1997 Amendment note below.

−MISC1−

AMENDMENTS

2002 − Par. (e). Pub. L. 107−188, Sec. 306(c)(1), substituted "by section 350a, 350c, 354, 373, or 374(a) of this title" for "by section 350a, 354, or 373 of this title" and "under section 350a, 350c(b)" for "under section 350a".

Par. (j). Pub. L. 107−188, Sec. 306(c)(2), inserted "350c," after "350a,".

Par. (w). Pub. L. 107−188, Sec. 322(b), amended par. (w) generally. Prior to amendment, par. (w) read as follows: "The making of a knowingly false statement in any record or report required or requested under subparagraph (A) or (B) of section 381(d)(3) of this title, the failure to submit or maintain records as required by sections 381(d)(3)(A) and 381(d)(3)(B) of this title, the release into interstate commerce of any article imported

into the United States under section 381(d)(3) of this title or any finished product made from such article (except for export in accordance with section 381(e) or 382 of this title or section 262(h) of title 42), or the failure to export or destroy any component, part or accessory not incorporated into a drug, biological product or device that will be exported in accordance with section 381(e) or 382 of this title or section 262(h) of title 42."

Par. (bb). Pub. L. 107−188, Sec. 303(b), added par. (bb).

Par. (cc). Pub. L. 107−188, Sec. 304(d), added par. (cc).

Par. (dd). Pub. L. 107−188, Sec. 305(b), added par. (dd).

Par. (ee). Pub. L. 107−188, Sec. 307(b), added par. (ee).

Par. (ff). Pub. L. 107−188, Sec. 321(b)(2), added par. (ff).

Par. (gg). Pub. L. 107−250 added par. (gg).

2000 − Par. (aa). Pub. L. 106−387 added par. (aa).

1997 − Par. (e). Pub. L. 105−115, Sec. 125(b)(2)(B), struck out "357(d) or (g)," after "355(i) or (k),".

Par. (i)(1). Pub. L. 105−115, Sec. 125(a)(2)(C), struck out ", 356, 357," before "or 379e of this title".

Par. (j). Pub. L. 105−115, Sec. 125(a)(2)(A), struck out "356, 357," before "360,".

Par. (l). Pub. L. 105−115, Sec. 421, struck out par. (l) which read as follows: "The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or suggestion that approval of an application with respect to such drug or device is in effect under section 355,

360e, or 360j(g) of this title, as the case may be, or that such drug or device complies with the provisions of such section."

Par. (x). Pub. L. 105−115, Sec. 204(b), added par. (x).

Par. (y). Pub. L. 105−115, Sec. 210(c), added par. (y).

Par. (z). Pub. L. 105−115, Sec. 401(b), (e), temporarily added par. (z). See Effective and Termination Dates of 1997 Amendment note below.

1996 − Par. (e). Pub. L. 104−250 inserted ", 354," before "or 373 of this title" and "354," before "355(i) or (k)".

Par. (j). Pub. L. 104−170 inserted before period at end of first sentence "; or the violating of section 346a(i)(2) of this title or any regulation issued under that section."

Pars. (u) to (w). Pub. L. 104−134 redesignated par. (u) relating to introduction into interstate commerce of unsafe dietary supplement as (v) and added par. (w).

1994 − Par. (e). Pub. L. 103−396, Sec. 2(b)(1)(A), substituted "357(d) or (g), 360b(a)(4)(C)," for "357(d) or (g),".

Par. (u). Pub. L. 103−417 added par. (u) relating to introduction into interstate commerce of unsafe dietary supplement.

Pub. L. 103−396, Sec. 2(b)(1)(B), added par. (u) relating to failure to comply with regulations or orders of Secretary.

1993 − Par. (j). Pub. L. 103−80, Sec. 3(c)(1), substituted "379, or 379e" for "379e, or 379".

Par. (s). Pub. L. 103−80, Sec. 3(c)(2), substituted "350a(e)" for "350a(d)".

1992 − Pars. (i)(1), (j). Pub. L. 102−571 substituted "379e"

for "376".

Par. (q)(1)(C). Pub. L. 102−300 added cl. (C).

1990 − Par. (e). Pub. L. 101−502 substituted "or (k)" for "or (j)".

Par. (j). Pub. L. 101−508 inserted at end "This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee."

1988 − Par. (t). Pub. L. 100−293 added par. (t).

1986 − Par. (s). Pub. L. 99−570 amended par. (s) generally. Prior to amendment, par. (s) read as follows: "The failure to provide the notice required by section 350a(b) or 350a(c), the failure to make the reports required by section 350a(d)(1)(B), or the failure to meet the requirements prescribed under section 350a(d)(2)."

1980 − Par. (e). Pub. L. 96−359, Sec. 5(b), inserted reference to section 350a of this title in two places.

Par. (j). Pub. L. 96−359, Sec. 5(c), inserted reference to section 350a of this title.

Par. (s). Pub. L. 96−359, Sec. 5(a), added par. (s).

1976 − Par. (e). Pub. L. 94−295, Sec. 3(b)(2), inserted references to sections 360e(f) and 360i of this title.

Par. (j). Pub. L. 94−295, Sec. 3(b)(3), inserted references to sections 360, 360c, 360d, 360e, 360f, 360h, 360i, 360j, and 379 of

this title.

Par. (l). Pub. L. 94−295, Sec. 3(b)(4), substituted "drug or device" for "drug" wherever appearing, and inserted references to sections 360e and 360j(g) of this title.

Par. (p). Pub. L. 94−295, Sec. 4(b)(1), substituted "section 360(j) or 360(k) of this title," for "section 360(j) of this title,".

Par. (q). Pub. L. 94−295, Sec. 3(b)(1), added par. (q).

Par. (r). Pub. L. 94−295, Sec. 7(b), added par. (r).

1972 − Par. (p). Pub. L. 92−387 added failure to provide information required by section 360(j) of this title, and failure to provide notice required by section 360(j)(2) of this title as prohibited acts.

1970 − Par. (q). Pub. L. 91−513 struck out par. (q) which set out penalties for illegal manufacture, sale, disposition, possession and other traffic in stimulant and depressant drugs. See section 801 et seq. of this title.

1968 − Par. (e). Pub. L. 90−399, Sec. 103(1), inserted reference to section 360b(j), (l), and (m) of this title.

Par. (j). Pub. L. 90−399, Sec. 103(2), inserted reference to section 360b of this title.

Par. (q). Pub. L. 90−639 divided cl. (3), which referred simply to possession in violation of section 360a(c) of this title, into subcls. (A) and (B) which refer, respectively, to possession in violation of section 360a(c)(1) of this title and possession in violation of section 360a(c)(2) of this title.

1965 − Par. (i). Pub. L. 89−74, Sec. 9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).

Par. (q). Pub. L. 89−74, Sec. 5, added par. (q).

1962 − Par. (e). Pub. L. 87−781, Sec. 103(c), 106(c), prohibited the failure to establish or maintain any record, or make any report, required under sections 355(i) or (j) and 507(d) or (g) of this title, or the refusal to permit access to, or verification or copying of, any such required record.

Par. (l). Pub. L. 87−781, Sec. 104(e)(1), inserted "approval of" before "an application", and substituted "in effect" for "effective".

Par. (o). Pub. L. 87−781, Sec. 114(a), added par. (o).

Par. (p). Pub. L. 87−781, Sec. 304, added par. (p).

1960 − Par. (i). Pub. L. 86−618, Sec. 105(a), struck out references to sections 346(b), 354, and 364 of this title and inserted reference to section 376 of this title.

Par. (j). Pub. L. 86−618, Sec. 104, inserted reference to section 376 of this title.

1958 − Par. (j). Pub. L. 85−929, inserted reference to section 348 of this title.

1953 − Par. (n). Act Aug. 7, 1953, added par. (n).

1950 − Par. (m). Act Mar. 16, 1950, added par. (m).

1948 − Par. (k). Act June 24, 1948, inserted "(whether or not the first sale)" so as to make it clear that this subsection is not limited to the case where the act occurs while the article is held for the first sale after interstate shipment, and extended

coverage of subsection to acts which result in adulteration.

1947 − Par. (j). Act Mar. 10, 1947, inserted reference to sections 356 and 357 of this title.

1945 − Par. (i). Act July 6, 1945, inserted reference to section 357 of this title.

1941 − Par. (i). Act Dec. 22, 1941, inserted reference to section 356 of this title.

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107−188, title III, Sec. 321(c), June 12, 2002, 116 Stat. 676, provided that: "The amendments made by this section (amending this section and sections 360 and 381 of this title) take effect upon the expiration of the 180−day period beginning on the date of the enactment of this Act (June 12, 2002)."

Pub. L. 107−188, title III, Sec. 322(c), June 12, 2002, 116 Stat. 678, provided that: "The amendments made by this section (amending this section and section 381 of this title) take effect upon the expiration of the 90−day period beginning on the date of the enactment of this Act (June 12, 2002)."

EFFECTIVE AND TERMINATION DATES OF 1997 AMENDMENT

Amendment by sections 204, 210, and 421 of Pub. L. 105−115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105−115, set out as a note under section 321 of this title.

Amendment by section 401(b) of Pub. L. 105−115 effective 1 year after Nov. 21, 1997, or upon Secretary's issuance of final regulations pursuant to section 401(c) of Pub. L. 105−115,

whichever is sooner, and ceases to be effective Sept. 30, 2006, or 7 years after date Secretary promulgates regulations under section 401(c) of Pub. L. 105−115, whichever is later, see section 401(d), (e) of Pub. L. 105−115, set out as an Effective and Termination Dates note under section 360aaa of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103−396 effective upon adoption of final regulations under section 2(c) of Pub. L. 103−396, set out as a Regulations note under section 360b of this title, see section 2(d) of Pub. L. 103−396, set out as a note under section 360b of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 4755(c)(2) of Pub. L. 101−508 provided that the amendment made by that section is effective as if included in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101−239, title VI, Sec. 6601, 6602, Dec. 19, 1989, 103 Stat. 2285, see 42 U.S.C. 300aa−1 note, 300aa−10 note.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100−293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100−293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1972 AMENDMENT

Amendment by Pub. L. 92−387 effective on first day of sixth month beginning after Aug. 16, 1972, see section 5 of Pub. L. 92−387, set out as a note under section 360 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91−513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91−513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENTS

Amendment by Pub. L. 90−399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90−399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

Amendment by Pub. L. 90−639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90−639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89−74 effective Feb. 1, 1966, see section 11 of Pub. L. 89−74, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by sections 103(c) and 106(c) of Pub. L. 87−781 effective on first day of seventh calendar month following Oct. 1962, and amendment by section 104(e)(1) of Pub. L. 87−781 effective Oct. 10, 1962, see section 107 of Pub. L. 87−781, set out as a note under section 321 of this title.

Section 114(b) of Pub. L. 87−781 provided that: "This section (amending this section) shall take effect on the first day of the

seventh calendar month following the month in which this Act is enacted (October 1962)."

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86−618 effective July 12, 1960, subject to provisions of section 203 of Pub. L. 86−618, see section 202 of Pub. L. 86−618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1958 AMENDMENT

Amendment by Pub. L. 85−929 effective Sept. 6, 1958, see section 6(a) of Pub. L. 85−929, set out as a note under section 342 of this title.

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of that act, set out as an Effective Date note under section 347 of this title.

REGULATIONS

Secretary of Health and Human Services to promulgate regulations to implement amendments made by section 401 of Pub. L. 105−115 not later than 1 year after Nov. 21, 1997, see section 401(c) of Pub. L. 105−115, set out as a note under section 360aaa of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91−513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) on Oct. 27, 1970,

to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91−513, set out as a note under section 321 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 107−188

Pub. L. 107−188, title III, Sec. 315, June 12, 2002, 116 Stat. 675, provided that: "Nothing in this title (enacting sections 350c, 350d, 398, 399, and 679c of this title, sections 3353, 3354, 8319, and 8320 of Title 7, Agriculture, and section 247b−20 of Title 42, The Public Health and Welfare, amending this section, sections 334, 335a, 342, 343, 360, 372, 374, and 381 of this title, and section 43 of Title 18, Crimes and Criminal Procedure, and enacting provisions set out as notes under this section and sections 341, 350c, 350d, and 381 of this title), or an amendment made by this title, shall be construed to alter the jurisdiction between the Secretaries of Agriculture and of Health and Human Services, under applicable statutes and regulations."

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 332, 333, 335a, 347b, 355a, 360, 360i, 360j, 360aaa of this title; title 42 section 1396r−8.

−CITE−

21 USC Sec. 332 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 332. Injunction proceedings

−STATUTE−

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown (FOOTNOTE 1) to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(FOOTNOTE 1) So in original. Probably should be followed by a comma.

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 302, 52 Stat. 1043; Pub. L. 87−781,

title I, Sec. 103(d), title II, Sec. 201(c), Oct. 10, 1962, 76 Stat. 784, 793; Pub. L. 103−80, Sec. 3(d), Aug. 13, 1993, 107 Stat. 775.)

−MISC1−

AMENDMENTS

1993 − Subsec. (a). Pub. L. 103−80, Sec. 3(d)(1), struck out ", and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled 'An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes', approved October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 381)," after "for cause shown".

Subsec. (b). Pub. L. 103−80, Sec. 3(d)(2), struck out at end "Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U.S.C., 1934 ed., title 28, sec. 387)."

1962 − Subsec. (a). Pub. L. 87−781, Sec. 103(d), struck out "(e)," after "paragraphs".

Pub. L. 87−781, Sec. 201(c), struck out "(f)," after "paragraphs".

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by section 103(c) of Pub. L. 87−781 effective on first day of seventh calendar month following October 1962, see section 107 of Pub. L. 87−781, set out as a note under section 321 of this title.

Section 203 of title II of Pub. L. 87−781 provided that: "The

amendments made by this title (amending this section and section 374 of this title and enacting provisions set out as notes under sections 321 and 374 of this title) shall take effect on the date of enactment of this Act (Oct. 10, 1962)."

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 334, 360j of this title; title 42 section 1396r−8.

−CITE−

21 USC Sec. 333 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 333. Penalties

−STATUTE−

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, (FOOTNOTE 1) if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person

shall be imprisoned for not more than three years or fined not more than $10,000, or both.

(FOOTNOTE 1) So in original. Words "of this section" probably should not appear.

(b) Prescription drug marketing violations

(1) Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title by −

(A) knowingly importing a drug in violation of section 381(d)(1) of this title,

(B) knowingly selling, purchasing, or trading a drug or drug sample or knowingly offering to sell, purchase, or trade a drug or drug sample, in violation of section 353(c)(1) of this title,

(C) knowingly selling, purchasing, or trading a coupon, knowingly offering to sell, purchase, or trade such a coupon, or knowingly counterfeiting such a coupon, in violation of section 353(c)(2) of this title, or

(D) knowingly distributing drugs in violation of section 353(e)(2)(A) of this title,

shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(2) Any manufacturer or distributor who distributes drug samples by means other than the mail or common carrier whose representative, during the course of the representative's employment or association with that manufacturer or distributor, violated section 331(t) of this title because of a violation of section 353(c)(1) of this title or violated any State law

prohibiting the sale, purchase, or trade of a drug sample subject to section 353(b) of this title or the offer to sell, purchase, or trade such a drug sample shall, upon conviction of the representative for such violation, be subject to the following civil penalties:

(A) A civil penalty of not more than $50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10−year period.

(B) A civil penalty of not more than $1,000,000 for each violation resulting in a conviction of any representative after the second conviction in any 10−year period.

For the purposes of this paragraph, multiple convictions of one or more persons arising out of the same event or transaction, or a related series of events or transactions, shall be considered as one violation.

(3) Any manufacturer or distributor who violates section 331(t) of this title because of a failure to make a report required by section 353(d)(3)(E) of this title shall be subject to a civil penalty of not more than $100,000.

(4)(A) If a manufacturer or distributor or any representative of such manufacturer or distributor provides information leading to the institution of a criminal proceeding against, and conviction of, any representative of that manufacturer or distributor for a violation of section 331(t) of this title because of a sale, purchase, or trade or offer to purchase, sell, or trade a drug

sample in violation of section 353(c)(1) of this title or for a violation of State law prohibiting the sale, purchase, or trade or offer to sell, purchase, or trade a drug sample, the conviction of such representative shall not be considered as a violation for purposes of paragraph (2).

(B) If, in an action brought under paragraph (2) against a manufacturer or distributor relating to the conviction of a representative of such manufacturer or distributor for the sale, purchase, or trade of a drug or the offer to sell, purchase, or trade a drug, it is shown, by clear and convincing evidence −

(i) that the manufacturer or distributor conducted, before the institution of a criminal proceeding against such representative for the violation which resulted in such conviction, an investigation of events or transactions which would have led to the reporting of information leading to the institution of a criminal proceeding against, and conviction of, such representative for such purchase, sale, or trade or offer to purchase, sell, or trade, or

(ii) that, except in the case of the conviction of a representative employed in a supervisory function, despite diligent implementation by the manufacturer or distributor of an independent audit and security system designed to detect such a violation, the manufacturer or distributor could not reasonably have been expected to have detected such violation,

the conviction of such representative shall not be considered as a conviction for purposes of paragraph (2).

(5) If a person provides information leading to the institution of a criminal proceeding against, and conviction of, a person for a violation of section 331(t) of this title because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample in violation of section 353(c)(1) of this title, such person shall be entitled to one−half of the criminal fine imposed and collected for such violation but not more than $125,000.

(6) Notwithstanding subsection (a) of this section, any person who is a manufacturer or importer of a covered product pursuant to section 384(a) of this title and knowingly fails to comply with a requirement of section 384(e) of this title that is applicable to such manufacturer or importer, respectively, shall be imprisoned for not more than 10 years or fined not more than $250,000, or both.

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 331(a) or (d) of this title, if he establishes a guaranty or undertaking signed by, and containing the

name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 331(a) of this title, that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 331(d) of this title, that such article is not an article which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce; or (3) for having violated section 331(a) of this title, where the violation exists because the article is adulterated by reason of containing a color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this chapter, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the color additive, to the effect that such color additive was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this chapter; or (4) for having violated section 331(b), (c) or (k) of this title by failure to comply with section 352(f) of this title in respect to an article received in interstate commerce to which neither section 353(a) nor 353(b)(1) of this title is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article; or (5) for having violated section 331(i)(2) of this title if such person acted in good faith and had

no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in a drug being a counterfeit drug, or for having violated section 331(i)(3) of this title if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the drug was a counterfeit drug.

(d) Exceptions involving misbranded food

No person shall be subject to the penalties of subsection (a)(1) of this section for a violation of section 331 of this title involving misbranded food if the violation exists solely because the food is misbranded under section 343(a)(2) of this title because of its advertising.

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the

Controlled Substances Act (21 U.S.C. 801 et seq.) for the purposes of forfeiture under section 413 of such Act (21 U.S.C. 853).

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Redesignated (g)

(g) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding. For purposes of the preceding sentence, a person accredited under paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices.

(B) Subparagraph (A) shall not apply −

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section

360i(e) or 360i(f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) Any person who introduces into interstate commerce or delivers for introduction into interstate commerce an article of food that is adulterated within the meaning of section 342(a)(2)(B) of this title shall be subject to a civil money penalty of not more than $50,000 in the case of an individual and $250,000 in the case of any other person for such introduction or delivery, not to exceed $500,000 for all such violations adjudicated in a single proceeding.

(B) This paragraph shall not apply to any person who grew the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the criminal authorities under this section to sanction such person for the introduction or delivery for introduction into interstate commerce of the article of food that is adulterated. If the Secretary assesses a civil penalty against any person under this paragraph, the Secretary may not use the seizure authorities of section 334 of this title or the injunction authorities of section 332 of this title with respect to the article of food that is adulterated.

(C) In a hearing to assess a civil penalty under this paragraph, the presiding officer shall have the same authority with regard to

compelling testimony or production of documents as a presiding officer has under section 346a(g)(2)(B) of this title. The third sentence of paragraph (3)(A) shall not apply to any investigation under this paragraph.

(3)(A) A civil penalty under paragraph (1) or (2) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1) or (2). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person

charged.

(4) Any person who requested, in accordance with paragraph (3)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60−day period beginning on the date the order making such assessment was issued.

(5) If any person fails to pay an assessment of a civil penalty −

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (4), or

(B) after a court in an action brought under paragraph (4) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60−day period referred to in paragraph (4) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 303, 52 Stat. 1043; Oct. 26, 1951, ch. 578, Sec. 2, 65 Stat. 649; Pub. L. 86−618, title I, Sec. 105(b), July 12, 1960, 74 Stat. 403; Pub. L. 89−74, Sec. 7, 9(d),

July 15, 1965, 79 Stat. 233, 235; Pub. L. 90−639, Sec. 3, Oct. 24, 1968, 82 Stat. 1361; Pub. L. 91−513, title II, Sec. 701(b), Oct. 27, 1970, 84 Stat. 1281; Pub. L. 94−278, title V, Sec. 502(a)(2)(B), Apr. 22, 1976, 90 Stat. 411; Pub. L. 100−293, Sec. 7(b), Apr. 22, 1988, 102 Stat. 99; Pub. L. 100−690, title II, Sec. 2403, Nov. 18, 1988, 102 Stat. 4230; Pub. L. 101−629, Sec. 17(a), Nov. 28, 1990, 104 Stat. 4526; Pub. L. 101−647, title XIX, Sec. 1904, Nov. 29, 1990, 104 Stat. 4853; Pub. L. 102−353, Sec. 3, Aug. 26, 1992, 106 Stat. 941; Pub. L. 103−80, Sec. 3(e), Aug. 13, 1993, 107 Stat. 775; Pub. L. 103−322, title XXXIII, Sec. 330015, Sept. 13, 1994, 108 Stat. 2146; Pub. L. 104−170, title IV, Sec. 407, Aug. 3, 1996, 110 Stat. 1535; Pub. L. 106−387, Sec. 1(a) (title VII, Sec. 745(d)(2)), Oct. 28, 2000, 114 Stat. 1549, 1549A−40; Pub. L. 107−250, title II, Sec. 201(c), Oct. 26, 2002, 116 Stat. 1609.)

−REFTEXT−

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (e)(3), is title II of Pub. L. 91−513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (Sec. 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

−MISC2−

AMENDMENTS

2002 − Subsec. (g)(1)(A). Pub. L. 107−250 inserted at end "For purposes of the preceding sentence, a person accredited under

paragraph (2) of section 374(g) of this title who is substantially not in compliance with the standards of accreditation under such section, or who poses a threat to public health or fails to act in a manner that is consistent with the purposes of such section, shall be considered to have violated a requirement of this chapter that relates to devices."

2000 − Subsec. (b)(6). Pub. L. 106−387 added par. (6).

1996 − Subsec. (g)(2). Pub. L. 104−170, Sec. 407(1), (2), added par. (2). Former par. (2) redesignated (3).

Subsec. (g)(3). Pub. L. 104−170, Sec. 407(1), (3), redesignated par. (2) as (3) and substituted "paragraph (1) or (2)" for "paragraph (1)" in subpars. (A) and (C). Former par. (3) redesignated (4).

Subsec. (g)(4). Pub. L. 104−170, Sec. 407(1), (4), redesignated par. (3) as (4) and substituted "paragraph (3)(A)" for "paragraph (2)(A)". Former par. (4) redesignated (5).

Subsec. (g)(5). Pub. L. 104−170, Sec. 407(1), (5), redesignated par. (4) as (5) and substituted "paragraph (4)" for "paragraph (3)" wherever appearing.

1994 − Subsec. (e). Pub. L. 103−322 amended directory language of Pub. L. 101−647. See 1990 Amendment note below.

1993 − Subsecs. (e) to (g). Pub. L. 103−80, which directed the amendment of this section by redesignating the second subsec. (e) and subsec. (f) as subsecs. (f) and (g), respectively, could only be executed by designating subsec. (f) as (g) because this section did not contain a second subsec. (e) subsequent to amendment of

Pub. L. 101−647 by Pub. L. 103−322. See 1990 and 1994 amendment notes for subsec. (e) under this section.

1992 − Subsec. (b)(1). Pub. L. 102−353, Sec. 3(a), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Notwithstanding subsection (a) of this section, any person who violates section 331(t) of this title because of an importation of a drug in violation of section 381(d)(1) of this title, because of a sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 353(c) of this title, because of the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 353(c)(2) of this title, or the distribution of drugs in violation of section 353(e)(2)(A) of this title shall be imprisoned for not more than 10 years or fined not more than $250,000, or both."

Subsec. (b)(4)(A). Pub. L. 102−353, Sec. 3(b)(1), substituted "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(4)(B)(i). Pub. L. 102−353, Sec. 3(b)(1), (2), substituted "before the institution of a criminal proceeding against" for "before the arrest of" and "the institution of a criminal proceeding against, and conviction of," for "the arrest and conviction of".

Subsec. (b)(5). Pub. L. 102−353, Sec. 3(b)(3), substituted "the institution of a criminal proceeding against, and conviction of,"

for "the arrest and conviction of".

Subsec. (c). Pub. L. 102−353, Sec. 3(b)(4), substituted "subsection (a)(1) of this section" for "subsection (a) of this section".

Subsec. (d). Pub. L. 102−353, Sec. 3(b)(4), (5), substituted "subsection (a)(1) of this section" for "subsection (a) of this section" and struck out ", and no person shall be subject to the penalties of subsection (b) of this section for such a violation unless the violation is committed with the intent to defraud or mislead" after "advertising".

1990 − Subsec. (e). Pub. L. 101−647, as amended by Pub. L. 103−322, amended subsec. (e) generally. Prior to amendment, subsec. (e) read as follows:

"(e)(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

"(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both."

Subsec. (f). Pub. L. 101−629 added subsec. (f).

1988 − Subsecs. (a), (b). Pub. L. 100−293 designated existing subsecs. (a) and (b) as pars. (1) and (2) of subsec. (a),

substituted "paragraph (1)" for "subsection (a)" in par. (2), and added subsec. (b).

Subsec. (e). Pub. L. 100−690 added subsec. (e).

1976 − Subsec. (d). Pub. L. 94−278 added subsec. (d).

1970 − Subsec. (a). Pub. L. 91−513 struck out reference to subsec. (b) and transferred to subsec. (b) provisions covering second offenses and offenses committed with intent to defraud or mislead.

Subsec. (b). Pub. L. 91−513 inserted provisions covering second offenses and offenses committed with intent to defraud or mislead formerly set out in subsec. (a) and struck out provisions covering violations involving depressant and stimulant drugs. See section 801 et seq. of this title.

1968 − Subsecs. (a), (b). Pub. L. 90−639 made a general revision in the penalties prescribed for offenses involving depressant or stimulant drugs, set a fine of not to exceed $10,000 or imprisonment of not more than 5 years for offenses involving the unlawful manufacturing of, sale, or disposal of, or possession with intent to sell, a depressant or stimulant drug or involving counterfeit depressant or stimulant drugs, stiffened the penalties for unlawful sales or other disposals by persons over 18 to persons under 21, and set new penalties for possession of a depressant or stimulant drug for purposes other than sale or other disposal.

1965 − Subsec. (a). Pub. L. 89−74, Sec. 7(a), inserted proviso limiting the penalties for depressant or stimulant drug violations to two years imprisonment or $5,000 fine or both for first offense

and to two years imprisonment or $15,000 fine or both for subsequent offenses.

Subsec. (b). Pub. L. 89−74, Sec. 7(b), inserted parenthetical exception provision.

Subsec. (c)(5). Pub. L. 89−74, Sec. 9(d), added cl. (5).

1960 − Subsec. (c)(3). Pub. L. 86−618 substituted "a color additive" for "a coal−tar color", "the color additive" for "the coal−tar color" and "such color additive was" for "such color was".

1951 − Subsec. (c)(4). Act Oct. 26, 1951, added cl. (4).

EFFECTIVE DATE OF 1994 AMENDMENT

Section 330015 of Pub. L. 103−322 provided that the amendment made by that section is effective as of the date on which section 1904 of Pub. L. 101−647, which amended this section, took effect.

EFFECTIVE DATE OF 1990 AMENDMENT

Section 17(b) of Pub. L. 101−629 provided that:

"(b) Effective Date of Application to Device User Facilities. −

"(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(b)) by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act (Nov. 28, 1990).

"(2)(A) If upon the expiration of 48 months after the date of

the enactment of this Act (Nov. 28, 1990) the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)), as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act). (Secretary of Health and Human Services had not made the report required by par. (1) on the expiration of 48 months after Nov. 28, 1990.)

"(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

"(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report."

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100−293 effective upon expiration of 90 days after Apr. 22, 1988, see section 8(a) of Pub. L. 100−293, set out as a note under section 353 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94−278 effective 180 days after Apr. 22, 1976, see section 502(c) of Pub. L. 94−278, set out as a note under section 334 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91−513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91−513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90−639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90−639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89−74 effective Feb. 1, 1966, see section 11 of Pub. L. 89−74, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86−618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86−618, see section 202 of Pub. L. 86−618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF 1951 AMENDMENT

Section 3 of act Oct. 26, 1951, provided that: "The provisions of this Act (amending this section and section 353 of this title)

shall take effect six months after the date of its enactment (Oct. 26, 1951)."

SAVINGS PROVISION

Amendment by Pub. L. 91−513 not to affect or abate any prosecutions for violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91−513, set out as a note under section 321 of this title.

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−MISC5−

ENFORCEMENT

Pub. L. 99−660, title I, Sec. 103, Nov. 14, 1986, 100 Stat. 3751, provided that: "For the fines authorized to be imposed under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), see section 3623 of title 18, United States Code, for the

period ending October 31, 1986 (probably should be October 31,

1987), and sections 3559 and 3571 of such title for the period

beginning November 1, 1986 (probably should be November 1, 1987)."

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 859 of this

title; title 15 section 1456.

−CITE−

21 USC Sec. 333a 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 333a. Repealed. Pub. L. 101−647, title XIX, Sec. 1905, Nov.

29, 1990, 104 Stat. 4853

−MISC1−

Section, Pub. L. 100−690, title II, Sec. 2401, Nov. 18, 1988, 102

Stat. 4230, related to forfeiture and illegal trafficking in

steroids or human growth hormones.

−CITE−

21 USC Sec. 334 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 334. Seizure

−STATUTE−

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 344 or 355 of this title, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. No libel for condemnation shall be instituted under this chapter, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this chapter based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (A) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this chapter, or (B) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is

fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found: (A) Any drug that is a counterfeit drug, (B) Any container of a counterfeit drug, (C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs, and (D) Any adulterated or misbranded device.

(3)(A) Except as provided in subparagraph (B), no libel for condemnation may be instituted under paragraph (1) or (2) against any food which −

(i) is misbranded under section 343(a)(2) of this title because

of its advertising, and

(ii) is being held for sale to the ultimate consumer in an establishment other than an establishment owned or operated by a manufacturer, packer, or distributor of the food.

(B) A libel for condemnation may be instituted under paragraph (1) or (2) against a food described in subparagraph (A) if −

(i)(I) the food's advertising which resulted in the food being misbranded under section 343(a)(2) of this title was disseminated in the establishment in which the food is being held for sale to the ultimate consumer,

(II) such advertising was disseminated by, or under the direction of, the owner or operator of such establishment, or

(III) all or part of the cost of such advertising was paid by such owner or operator; and

(ii) the owner or operator of such establishment used such advertising in the establishment to promote the sale of the food.

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the

claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

(c) Availability of samples of seized goods prior to trial

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for

remission or mitigation of forfeitures

(1) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this chapter or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this chapter or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes (A) that the adulteration, misbranding, or violation did not occur after the article was imported, and (B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody, the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the

conditions of section 381(e) of this title can and will be met. The provisions of this sentence shall not apply where condemnation is based upon violation of section 342(a)(1), (2), or (6), section 351(a)(3), section 352(j), or section 361(a) or (d) of this title. Where such exportation is made to the original foreign supplier, then subparagraphs (A) and (B) of section 381(e)(1) of this title and the preceding sentence shall not be applicable; and in all cases of exportation the bond shall be conditioned that the article shall not be sold or disposed of until the applicable conditions of section 381(e) of this title have been met. Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce. Any article condemned by reason of its being an article which may not, under section 344 or 355 of this title, be introduced into interstate commerce, shall be disposed of by destruction.

(2) The provisions of paragraph (1) of this subsection shall, to the extent deemed appropriate by the court, apply to any equipment or other thing which is not otherwise within the scope of such paragraph and which is referred to in paragraph (2) of subsection (a) of this section.

(3) Whenever in any proceeding under this section, involving paragraph (2) of subsection (a) of this section, the condemnation of any equipment or thing (other than a drug) is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture

if such claimant proves to the satisfaction of the court (i) that he has not committed or caused to be committed any prohibited act referred to in such paragraph (2) and has no interest in any drug referred to therein, (ii) that he has an interest in such equipment or other thing as owner or lienor or otherwise, acquired by him in good faith, and (iii) that he at no time had any knowledge or reason to believe that such equipment or other thing was being or would be used in, or to facilitate, the violation of laws of the United States relating to counterfeit drugs.

(e) Costs

When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

(f) Removal of case for trial

In the case of removal for trial of any case as provided by subsection (a) or (b) of this section −

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

(g) Administrative restraint; detention orders

(1) If during an inspection conducted under section 374 of this title of a facility or a vehicle, a device which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) of this section or section 332 of this title, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device during the period of its detention for the purpose of identifying the device as detained. Any person who would be entitled to claim a device if it were seized under subsection (a) of this section may appeal to the Secretary a detention of such device under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

(2)(A) Except as authorized by subparagraph (B), a device subject to a detention order issued under paragraph (1) shall not be moved

by any person from the place at which it is ordered detained until –

(i) released by the Secretary, or

(ii) the expiration of the detention period applicable to such order,

whichever occurs first.

(B) A device subject to a detention order under paragraph (1) may be moved −

(i) in accordance with regulations prescribed by the Secretary, and

(ii) if not in final form for shipment, at the discretion of the manufacturer of the device for the purpose of completing the work required to put it in such form.

(h) Administrative detention of foods

(1) Detention authority

(A) In general

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this chapter conducted by such officer or qualified employee, if the officer or qualified employee has credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals.

(B) Secretary's approval

An article of food may be ordered detained under subparagraph

(A) only if the Secretary or an official designated by the Secretary approves the order. An official may not be so designated unless the official is the director of the district under this chapter in which the article involved is located, or is an official senior to such director.

(2) Period of detention

An article of food may be detained under paragraph (1) for a reasonable period, not to exceed 20 days, unless a greater period, not to exceed 30 days, is necessary, to enable the Secretary to institute an action under subsection (a) of this section or section 332 of this title. The Secretary shall by regulation provide for procedures for instituting such action on an expedited basis with respect to perishable foods.

(3) Security of detained article

An order under paragraph (1) with respect to an article of food may require that such article be labeled or marked as detained, and shall require that the article be removed to a secure facility, as appropriate. An article subject to such an order shall not be transferred by any person from the place at which the article is ordered detained, or from the place to which the article is so removed, as the case may be, until released by the Secretary or until the expiration of the detention period applicable under such order, whichever occurs first. This subsection may not be construed as authorizing the delivery of the article pursuant to the execution of a bond while the article is subject to the order, and section 381(b) of this title does

not authorize the delivery of the article pursuant to the execution of a bond while the article is subject to the order.

(4) Appeal of detention order

(A) In general

With respect to an article of food ordered detained under paragraph (1), any person who would be entitled to be a claimant for such article if the article were seized under subsection (a) of this section may appeal the order to the Secretary. Within five days after such an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order involved, and such confirmation by the Secretary shall be considered a final agency action for purposes of section 702 of title 5. If during such five−day period the Secretary fails to provide such an opportunity, or to confirm or terminate such order, the order is deemed to be terminated.

(B) Effect of instituting court action

The process under subparagraph (A) for the appeal of an order under paragraph (1) terminates if the Secretary institutes an action under subsection (a) of this section or section 332 of this title regarding the article of food involved.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 304, 52 Stat. 1044; June 24, 1948, ch. 613, Sec. 2, 62 Stat. 582; Aug. 7, 1953, ch. 350, Sec. 3, 67 Stat. 477; Pub. L. 85−250, Aug. 31, 1957, 71 Stat. 567; Pub. L. 89−74, Sec. 6, July 15, 1965, 79 Stat. 232; Pub. L. 90−639, Sec.

4(b), Oct. 24, 1968, 82 Stat. 1362; Pub. L. 91−513, title II, Sec. 701(c), (d), Oct. 27, 1970, 84 Stat. 1281, 1282; Pub. L. 94−278, title V, Sec. 502(a)(2)(C), Apr. 22, 1976, 90 Stat. 411; Pub. L. 94−295, Sec. 3(c), 7(a), May 28, 1976, 90 Stat. 576, 582; Pub. L. 102−300, Sec. 6(c), June 16, 1992, 106 Stat. 240; Pub. L. 103−80, Sec. 3(f), Aug. 13, 1993, 107 Stat. 775; Pub. L. 105−115, title IV, Sec. 418, Nov. 21, 1997, 111 Stat. 2379; Pub. L. 107−188, title III, Sec. 303(a), June 12, 2002, 116 Stat. 663.)

−MISC1−

AMENDMENTS

2002 − Subsec. (h). Pub. L. 107−188 added subsec. (h).

1997 − Subsec. (d)(1). Pub. L. 105−115 substituted "subparagraphs (A) and (B) of section 381(e)(1) of this title" for "paragraphs (1) and (2) of section 381(e) of this title" and inserted "Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce." before "Any article condemned by reason".

1993 − Subsec. (a)(1). Pub. L. 103−80, Sec. 3(f)(1), substituted "found. No libel" for "found: Provided, however, That no libel".

Subsec. (d)(1). Pub. L. 103−80, Sec. 3(f)(2), substituted "sold. After entry" for "sold: Provided, That after entry", "met. The provisions of this sentence" for "met: Provided, however, That the provisions of this sentence", "title. Where such

exportation" for "title: And provided further, That where such exportation", and "the preceding sentence shall not be applicable" for "the foregoing proviso shall not be applicable".

1992 − Subsec. (d)(1). Pub. L. 102−300 substituted "381(e)" for "381(d)" in three places and "paragraphs" for "clauses" before "(1) and (2) of section 381(e)".

1976 − Subsec. (a)(1). Pub. L. 94−295, Sec. 3(c)(1), struck out "device," after "Any article of food, drug,".

Subsec. (a)(2). Pub. L. 94−295, Sec. 3(c)(2), (3), added cl. (D) covering adulterated or misbranded devices.

Subsec. (a)(3). Pub. L. 94−278 added par. (3).

Subsec. (g). Pub. L. 94−295, Sec. 7(a), added subsec. (g).

1970 − Subsec. (a)(2). Pub. L. 91−513, Sec. 701(c), struck out cls. (A) and (D) which dealt with depressant or stimulant drugs, struck out reference to depressant or stimulant drugs in cl. (C), and redesignated cls. (B), (C), and (E) as cls. (A), (B), and (C), respectively.

Subsec. (d)(3)(iii). Pub. L. 91−513, Sec. 701(d), struck out reference to depressant or stimulant drugs.

1968 − Subsec. (a). Pub. L. 90−639 inserted references to the United States courts of Territories.

1965 − Subsec. (a). Pub. L. 89−74, Sec. 6(a), designated existing provisions as par. (1), redesignated cls. (1) and (2) of proviso as (A) and (B), and added par. (2).

Subsec. (b). Pub. L. 89−74, Sec. 6(b)(1), inserted "equipment, or other thing proceeded against" after "article" in first

sentence.

Subsec. (d). Pub. L. 89−74, Sec. 6(b)(2), designated existing provisions as par. (1), redesignated cls. (1) and (2) of the second sentence thereof as (A) and (B), and added pars. (2) and (3).

1957 − Subsec. (d). Pub. L. 85−250 permitted, under certain circumstances, reexportation of articles condemned at places other than original port of entry.

1953 − Subsec. (c). Act Aug. 7, 1953, provided that a true copy of the analysis in any case shall be furnished the owner.

1948 − Subsec. (a). Act June 24, 1948, inserted "or while held for sale (whether or not the first sale) after shipment in interstate commerce" to make this subsection coextensive with section 331(k) of this title.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105−115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105−115, set out as a note under section 321 of this title.

EFFECTIVE DATE OF 1976 AMENDMENT

Section 502(c) of Pub. L. 94−278 provided that: "The amendments made by subsection (a) (amending this section and sections 321, 333, and 343 of this title) shall take effect 180 days after the date of the enactment of this Act (Apr. 22, 1976)."

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91−513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91−513, set out as an Effective Date note under section 801

of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90−639 applicable only with respect to violations of this chapter committed after Oct. 24, 1968, see section 6 of Pub. L. 90−639, set out as an Effective Date of 1968 Amendments; Transitional Provisions note under section 321 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89−74 effective Feb. 1, 1966, see section 11 of Pub. L. 89−74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91−513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs (now the Drug Enforcement Administration) on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91−513, set out as a note under section 321 of this title.

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human

Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 360j, 372 of this title; title 42 section 1396r−8.

−CITE−

21 USC Sec. 335 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 335. Hearing before report of criminal violation

−STATUTE−

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 305, 52 Stat. 1045.)

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−CITE−

21 USC Sec. 335a 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 335a. Debarment, temporary denial of approval, and suspension

−STATUTE−

(a) Mandatory debarment; certain drug applications

(1) Corporations, partnerships, and associations

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) Individuals

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct −

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this chapter,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

(b) Permissive debarment; certain drug applications; food imports

(1) In general

The Secretary, on the Secretary's own initiative or in response to a petition, may, in accordance with paragraph (2), debar −

(A) a person other than an individual from submitting or assisting in the submission of any abbreviated drug application,

(B) an individual from providing services in any capacity to a person that has an approved or pending drug product application, or

(C) a person from importing an article of food or offering such an article for import into the United States.

(2) Persons subject to permissive debarment; certain drug applications

The following persons are subject to debarment under subparagraph (A) or (B) of paragraph (1):

(A) Corporations, partnerships, and associations

Any person other than an individual that the Secretary finds has been convicted −

(i) for conduct that −

(I) relates to the development or approval, including the process for the development or approval, of any abbreviated drug application; and

(II) is a felony under Federal law (if the person was convicted before May 13, 1992), a misdemeanor under Federal law, or a felony under State law, or

(ii) of a conspiracy to commit, or aiding or abetting, a criminal offense described in clause (i) or a felony described in subsection (a)(1) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the regulation of drugs.

(B) Individuals

(i) Any individual whom the Secretary finds has been convicted of −

(I) a misdemeanor under Federal law or a felony under State law for conduct relating to the development or approval, including the process for development or approval, of any drug product or otherwise relating to the regulation of drug products under this chapter, or

(II) a conspiracy to commit, or aiding or abetting, such criminal offense or a felony described in subsection (a)(2) of this section,

if the Secretary finds that the type of conduct which served as the basis for such conviction undermines the process for the

regulation of drugs.

(ii) Any individual whom the Secretary finds has been convicted of −

(I) a felony which is not described in subsection (a)(2) of this section or clause (i) of this subparagraph and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records, or interference with, obstruction of an investigation into, or prosecution of, any criminal offense, or

(II) a conspiracy to commit, or aiding or abetting, such felony,

if the Secretary finds, on the basis of the conviction of such individual and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iii) Any individual whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in subsection (a) of this section or in clause (i) or (ii) for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such individual may violate requirements under this chapter relating to drug products.

(iv) Any high managerial agent whom the Secretary finds −

(I) worked for, or worked as a consultant for, the same person as another individual during the period in which such other individual took actions for which a felony conviction was obtained and which resulted in the debarment under subsection (a)(2) of this section, or clause (i), of such other individual,

(II) had actual knowledge of the actions described in subclause (I) of such other individual, or took action to avoid such actual knowledge, or failed to take action for the purpose of avoiding such actual knowledge,

(III) knew that the actions described in subclause (I) were violative of law, and

(IV) did not report such actions, or did not cause such actions to be reported, to an officer, employee, or agent of the Department or to an appropriate law enforcement officer, or failed to take other appropriate action that would have ensured that the process for the regulation of drugs was not undermined, within a reasonable time after such agent first knew of such actions,

if the Secretary finds that the type of conduct which served as the basis for such other individual's conviction undermines the process for the regulation of drugs.

(3) Persons subject to permissive debarment; food importation

A person is subject to debarment under paragraph (1)(C) if −

(A) the person has been convicted of a felony for conduct

relating to the importation into the United States of any food; or

(B) the person has engaged in a pattern of importing or offering for import adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

(4) Stay of certain orders

An order of the Secretary under clause (iii) or (iv) of paragraph (2)(B) shall not take effect until 30 days after the order has been issued.

(c) Debarment period and considerations

(1) Effect of debarment

The Secretary −

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) of this section during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B) of this section, debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in

paragraph (6) or (7) of section 335b(a) of this title, assess a civil penalty in accordance with section 335b of this title.

(2) Debarment periods

(A) In general

The Secretary shall debar a person under subsection (a) or (b) of this section for the following periods:

(i) The period of debarment of a person (other than an individual) under subsection (a)(1) of this section shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under subsection (a) of this section occurs within 10 years after such person has been debarred under subsection (a)(1) of this section, the period of debarment shall be permanent.

(ii) The debarment of an individual under subsection (a)(2) of this section shall be permanent.

(iii) The period of debarment of any person under paragraph (2) or (3) of subsection (b) of this section shall not be more than 5 years.

The Secretary may determine whether debarment periods shall run concurrently or consecutively in the case of a person debarred for multiple offenses.

(B) Notification

Upon a conviction for an offense described in subsection (a) or (b) of this section or upon execution of an agreement with the United States to plead guilty to such an offense, the person involved may notify the Secretary that the person

acquiesces to debarment and such person's debarment shall commence upon such notification.

(3) Considerations

In determining the appropriateness and the period of a debarment of a person under subsection (b) of this section and any period of debarment beyond the minimum specified in subparagraph (A)(i) of paragraph (2), the Secretary shall consider where applicable −

(A) the nature and seriousness of any offense involved,

(B) the nature and extent of management participation in any offense involved, whether corporate policies and practices encouraged the offense, including whether inadequate institutional controls contributed to the offense,

(C) the nature and extent of voluntary steps to mitigate the impact on the public of any offense involved, including the recall or the discontinuation of the distribution of suspect drugs, full cooperation with any investigations (including the extent of disclosure to appropriate authorities of all wrongdoing), the relinquishing of profits on drug approvals fraudulently obtained, and any other actions taken to substantially limit potential or actual adverse effects on the public health,

(D) whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,

(E) whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements, and

(F) prior convictions under this chapter or under other Acts involving matters within the jurisdiction of the Food and Drug Administration.

(d) Termination of debarment

(1) Application

Any person that is debarred under subsection (a) of this section (other than a person permanently debarred) or any person that is debarred under subsection (b) of this section may apply to the Secretary for termination of the debarment under this subsection. Any information submitted to the Secretary under this paragraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(2) Deadline

The Secretary shall grant or deny any application respecting a debarment which is submitted under paragraph (1) within 180 days of the date the application is submitted.

(3) Action by the Secretary

(A) Corporations

(i) Conviction reversal

If the conviction which served as the basis for the debarment of a person under subsection (a)(1) of this section

or paragraph (2)(A) or (3) of subsection (b) of this section is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of a person if the Secretary finds that −

(I) changes in ownership, management, or operations have fully corrected the causes of the offense involved and provide reasonable assurances that the offense will not occur in the future, and

(II) in applicable cases, sufficient audits, conducted by the Food and Drug Administration or by independent experts acceptable to the Food and Drug Administration, demonstrate that pending applications and the development of drugs being tested before the submission of an application are free of fraud or material false statements.

In the case of persons debarred under subsection (a)(1) of this section, such termination shall take effect no earlier than the expiration of one year from the date of the debarment.

(B) Individuals

(i) Conviction reversal

If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) of this section or clause (i), (ii), (iii), or (iv) of subsection

(b)(2)(B) or subsection (b)(3) of this section is reversed, the Secretary shall withdraw the order of debarment.

(ii) Application

Upon application submitted under paragraph (1), the Secretary shall terminate the debarment of an individual who has been debarred under subsection (b)(2)(B) or subsection (b)(3) of this section if such termination serves the interests of justice and adequately protects the integrity of the drug approval process or the food importation process, as the case may be.

(4) Special termination

(A) Application

Any person that is debarred under subsection (a)(1) of this section (other than a person permanently debarred under subsection (c)(2)(A)(i) of this section) or any individual who is debarred under subsection (a)(2) of this section may apply to the Secretary for special termination of debarment under this subsection. Any information submitted to the Secretary under this subparagraph does not constitute an amendment or supplement to pending or approved abbreviated drug applications.

(B) Corporations

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that −

(i) the person making the application under subparagraph

(A) has demonstrated that the felony conviction which was the basis for such person's debarment involved the commission of an offense which was not authorized, requested, commanded, performed, or recklessly tolerated by the board of directors or by a high managerial agent acting on behalf of the person within the scope of the board's or agent's office or employment,

(ii) all individuals who were involved in the commission of the offense or who knew or should have known of the offense have been removed from employment involving the development or approval of any drug subject to sections (FOOTNOTE 1) 355 of this title,

(FOOTNOTE 1) So in original. Probably should be "section".

(iii) the person fully cooperated with all investigations and promptly disclosed all wrongdoing to the appropriate authorities, and

(iv) the person acted to mitigate any impact on the public of any offense involved, including the recall, or the discontinuation of the distribution, of any drug with respect to which the Secretary requested a recall or discontinuation of distribution due to concerns about the safety or efficacy of the drug.

(C) Individuals

Upon an application submitted under subparagraph (A), the Secretary may take the action described in subparagraph (D) if the Secretary, after an informal hearing, finds that such

individual has provided substantial assistance in the investigations or prosecutions of offenses which are described in subsection (a) or (b) of this section or which relate to any matter under the jurisdiction of the Food and Drug Administration.

(D) Secretarial action

The action referred to in subparagraphs (B) and (C) is −

(i) in the case of a person other than an individual −

(I) terminating the debarment immediately, or

(II) limiting the period of debarment to less than one year, and

(ii) in the case of an individual, limiting the period of debarment to less than permanent but to no less than 1 year, whichever best serves the interest of justice and protects the integrity of the drug approval process.

(e) Publication and list of debarred persons

The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b) of this section, the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

(f) Temporary denial of approval

(1) In general

The Secretary, on the Secretary's own initiative or in response

to a petition, may, in accordance with paragraph (3), refuse by order, for the period prescribed by paragraph (2), to approve any abbreviated drug application submitted by any person −

(A) if such person is under an active Federal criminal investigation in connection with an action described in subparagraph (B),

(B) if the Secretary finds that such person −

(i) has bribed or attempted to bribe, has paid or attempted to pay an illegal gratuity, or has induced or attempted to induce another person to bribe or pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services or to any other Federal, State, or local official in connection with any abbreviated drug application, or has conspired to commit, or aided or abetted, such actions, or

(ii) has knowingly made or caused to be made a pattern or practice of false statements or misrepresentations with respect to material facts relating to any abbreviated drug application, or the production of any drug subject to an abbreviated drug application, to any officer, employee, or agent of the Department of Health and Human Services, or has conspired to commit, or aided or abetted, such actions, and

(C) if a significant question has been raised regarding −

(i) the integrity of the approval process with respect to such abbreviated drug application, or

(ii) the reliability of data in or concerning such person's

abbreviated drug application.

Such an order may be modified or terminated at any time.

(2) Applicable period

(A) In general

Except as provided in subparagraph (B), a denial of approval of an application of a person under paragraph (1) shall be in effect for a period determined by the Secretary but not to exceed 18 months beginning on the date the Secretary finds that the conditions described in subparagraphs (A), (B), and (C) of paragraph (1) exist. The Secretary shall terminate such denial –

(i) if the investigation with respect to which the finding was made does not result in a criminal charge against such person, if criminal charges have been brought and the charges have been dismissed, or if a judgment of acquittal has been entered, or

(ii) if the Secretary determines that such finding was in error.

(B) Extension

If, at the end of the period described in subparagraph (A), the Secretary determines that a person has been criminally charged for an action described in subparagraph (B) of paragraph (1), the Secretary may extend the period of denial of approval of an application for a period not to exceed 18 months. The Secretary shall terminate such extension if the charges have been dismissed, if a judgment of acquittal has

been entered, or if the Secretary determines that the finding described in subparagraph (A) was in error.

(3) Informal hearing

Within 10 days of the date an order is issued under paragraph (1), the Secretary shall provide such person with an opportunity for an informal hearing, to be held within such 10 days, on the decision of the Secretary to refuse approval of an abbreviated drug application. Within 60 days of the date on which such hearing is held, the Secretary shall notify the person given such hearing whether the Secretary's refusal of approval will be continued, terminated, or otherwise modified. Such notification shall be final agency action.

(g) Suspension authority

(1) In general

If −

(A) the Secretary finds −

(i) that a person has engaged in conduct described in subparagraph (B) of subsection (f)(1) of this section in connection with 2 or more drugs under abbreviated drug applications, or

(ii) that a person has engaged in flagrant and repeated, material violations of good manufacturing practice or good laboratory practice in connection with the development, manufacturing, or distribution of one or more drugs approved under an abbreviated drug application during a 2−year period, and −

(I) such violations may undermine the safety and efficacy of such drugs, and

(II) the causes of such violations have not been corrected within a reasonable period of time following notice of such violations by the Secretary, and

(B) such person is under an active investigation by a Federal authority in connection with a civil or criminal action involving conduct described in subparagraph (A),

the Secretary shall issue an order suspending the distribution of all drugs the development or approval of which was related to such conduct described in subparagraph (A) or suspending the distribution of all drugs approved under abbreviated drug applications of such person if the Secretary finds that such conduct may have affected the development or approval of a significant number of drugs which the Secretary is unable to identify. The Secretary shall exclude a drug from such order if the Secretary determines that such conduct was not likely to have influenced the safety or efficacy of such drug.

(2) Public health waiver

The Secretary shall, on the Secretary's own initiative or in response to a petition, waive the suspension under paragraph (1) (involving an action described in paragraph (1)(A)(i)) with respect to any drug if the Secretary finds that such waiver is necessary to protect the public health because sufficient quantities of the drug would not otherwise be available. The Secretary shall act on any petition seeking action under this

paragraph within 180 days of the date the petition is submitted to the Secretary.

(h) Termination of suspension

The Secretary shall withdraw an order of suspension of the distribution of a drug under subsection (g) of this section if the person with respect to whom the order was issued demonstrates in a petition to the Secretary −

(1)(A) on the basis of an audit by the Food and Drug Administration or by experts acceptable to the Food and Drug Administration, or on the basis of other information, that the development, approval, manufacturing, and distribution of such drug is in substantial compliance with the applicable requirements of this chapter, and

(B) changes in ownership, management, or operations −

(i) fully remedy the patterns or practices with respect to which the order was issued, and

(ii) provide reasonable assurances that such actions will not occur in the future, or

(2) the initial determination was in error.

The Secretary shall act on a submission of a petition under this subsection within 180 days of the date of its submission and the Secretary may consider the petition concurrently with the suspension proceeding. Any information submitted to the Secretary under this subsection does not constitute an amendment or supplement to a pending or approved abbreviated drug application.

(i) Procedure

The Secretary may not take any action under subsection (a), (b), (c), (d)(3), (g), or (h) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(j) Judicial review

(1) In general

Except as provided in paragraph (2), any person that is the subject of an adverse decision under subsection (a), (b), (c), (d), (f), (g), or (h) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(2) Exception

Any person that is the subject of an adverse decision under clause (iii) or (iv) of subsection (b)(2)(B) of this section may obtain a review of such decision by the United States District Court for the District of Columbia or a district court of the United States for the district in which the person resides, by

filing in such court (within 30 days following the date the person is notified of the Secretary's decision) a complaint requesting that the decision be modified or set aside. In such an action, the court shall determine the matter de novo.

(k) Certification

Any application for approval of a drug product shall include −

(1) a certification that the applicant did not and will not use in any capacity the services of any person debarred under subsection (a) or (b) of this section, in connection with such application, and

(2) if such application is an abbreviated drug application, a list of all convictions, described in subsections (a) and (b) of this section which occurred within the previous 5 years, of the applicant and affiliated persons responsible for the development or submission of such application.

(l) Applicability

(1) Conviction

For purposes of this section, a person is considered to have been convicted of a criminal offense −

(A) when a judgment of conviction has been entered against the person by a Federal or State court, regardless of whether there is an appeal pending,

(B) when a plea of guilty or nolo contendere by the person has been accepted by a Federal or State court, or

(C) when the person has entered into participation in a first offender, deferred adjudication, or other similar arrangement

or program where judgment of conviction has been withheld.

(2) Effective dates

Subsection (a) of this section, subparagraph (A) of subsection (b)(2) of this section, clauses (i) and (ii) of subsection (b)(2)(B) of this section, and subsection (b)(3)(A) of this section shall not apply to a conviction which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (a) or (b) of this section. Clauses (iii) and (iv) of subsection (b)(2)(B) of this section, subsection (b)(3)(B) of this section, and subsections (f) and (g) of this section shall not apply to an act or action which occurred more than 5 years before the initiation of an agency action proposed to be taken under subsection (b), (f), or (g) of this section. Clause (iv) of subsection (b)(2)(B) of this section shall not apply to an action which occurred before June 1, 1992. Subsection (k) of this section shall not apply to applications submitted to the Secretary before June 1, 1992.

(m) Devices; mandatory debarment regarding third−party inspections and reviews

(1) In general

If the Secretary finds that a person has been convicted of a felony under section 331(gg) of this title, the Secretary shall debar such person from being accredited under section 360m(b) or 374(g)(2) of this title and from carrying out activities under an agreement described in section 383(b) of this title.

(2) Debarment period

The Secretary shall debar a person under paragraph (1) for the following periods:

(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

(B) The debarment of an individual shall be permanent.

(3) Termination of debarment; judicial review; other matters

Subsections (c)(3), (d), (e), (i), (j), and (l)(1) of this section apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1) of this section, or an individual who is debarred under subsection (a)(2) of this section, respectively.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 306, as added Pub. L. 102−282, Sec. 2, May 13, 1992, 106 Stat. 150; amended Pub. L. 105−115, title I, Sec. 125(b)(2)(C), Nov. 21, 1997, 111 Stat. 2325; Pub. L. 107−188, title III, Sec. 304(a)−(c), June 12, 2002, 116 Stat. 665, 666; Pub. L. 107−250, title II, Sec. 203, Oct. 26, 2002, 116 Stat. 1610.)

−MISC1−

PRIOR PROVISIONS

A prior section 306 of act June 25, 1938, was renumbered section

309 and is classified to section 336 of this title.

AMENDMENTS

2002 − Subsec. (a). Pub. L. 107−188, Sec. 304(b)(1), substituted "Mandatory debarment; certain drug applications" for "Mandatory debarment" in heading.

Subsec. (b). Pub. L. 107−188, Sec. 304(b)(2)(A), substituted "Permissive debarment; certain drug applications; food imports" for "Permissive debarment" in heading.

Subsec. (b)(1)(C). Pub. L. 107−188, Sec. 304(a)(1), added subpar. (C).

Subsec. (b)(2). Pub. L. 107−188, Sec. 304(b)(2)(B), substituted "permissive debarment; certain drug applications" for "permissive debarment" in heading.

Pub. L. 107−188, Sec. 304(a)(2)(A), inserted "subparagraph (A) or (B) of" before "paragraph (1)" in introductory provisions.

Subsec. (b)(3), (4). Pub. L. 107−188, Sec. 304(a)(2)(B), (C), added par. (3) and redesignated former par. (3) as (4).

Subsec. (c)(2)(A)(iii). Pub. L. 107−188, Sec. 304(b)(3), substituted "paragraph (2) or (3) of subsection (b)" for "subsection (b)(2)".

Subsec. (d)(3)(A)(i). Pub. L. 107−188, Sec. 304(b)(4)(A), substituted "subsection (a)(1) of this section or paragraph (2)(A) or (3) of subsection (b)" for "subsection (a)(1) or (b)(2)(A)".

Subsec. (d)(3)(A)(ii)(II). Pub. L. 107−188, Sec. 304(b)(4)(B), inserted "in applicable cases," before "sufficient audits".

Subsec. (d)(3)(B)(i). Pub. L. 107−188, Sec. 304(b)(4)(C),

inserted "or subsection (b)(3)" after "subsection (b)(2)(B)".

Subsec. (d)(3)(B)(ii). Pub. L. 107−188, Sec. 304(b)(4)(C), (D), inserted "or subsection (b)(3)" after "subsection (b)(2)(B)" and "or the food importation process, as the case may be" before period.

Subsec. (l)(2). Pub. L. 107−188, Sec. 304(c), in first sentence struck out "and" after "subsection (b)(2) of this section," and inserted ", and subsection (b)(3)(A) of this section" after "subsection (b)(2)(B) of this section" and in second sentence inserted ", subsection (b)(3)(B) of this section," after "subsection (b)(2)(B) of this section".

Subsec. (m). Pub. L. 107−250 added subsec. (m).

1997 − Subsec. (d)(4)(B)(ii). Pub. L. 105−115 struck out "or 357" after "355".

CONSTRUCTION

Section 7 of Pub. L. 102−282 provided that: "No amendment made by this Act (enacting this section and sections 335b and 335c of this title and amending sections 321, 336, 337, and 355 of this title) shall preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by this Act."

CONGRESSIONAL FINDINGS

Section 1(c) of Pub. L. 102−282 provided that: "The Congress finds that −

"(1) there is substantial evidence that significant corruption

occurred in the Food and Drug Administration's process of approving drugs under abbreviated drug applications,

"(2) there is a need to establish procedures designed to restore and to ensure the integrity of the abbreviated drug application approval process and to protect the public health, and

"(3) there is a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products."

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 335b, 381 of this title.

−CITE−

21 USC Sec. 335b 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 335b. Civil penalties

−STATUTE−

(a) In general

Any person that the Secretary finds −

(1) knowingly made or caused to be made, to any officer,

employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly −

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under section 335a of this title, or

(7) is an individual debarred under section 335a of this title and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

(b) Procedure

(1) In general

(A) Action by the Secretary

A civil penalty under subsection (a) of this section shall be assessed by the Secretary on a person by an order made on the record after an opportunity for an agency hearing on disputed issues of material fact and the amount of the penalty. In the course of any investigation or hearing under this subparagraph, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(B) Action by the Attorney General

In lieu of a proceeding under subparagraph (A), the Attorney General may, upon request of the Secretary, institute a civil action to recover a civil money penalty in the amount and for any of the acts set forth in subsection (a) of this section. Such an action may be instituted separately from or in connection with any other claim, civil or criminal, initiated

by the Attorney General under this chapter.

(2) Amount

In determining the amount of a civil penalty under paragraph (1), the Secretary or the court shall take into account the nature, circumstances, extent, and gravity of the act subject to penalty, the person's ability to pay, the effect on the person's ability to continue to do business, any history of prior, similar acts, and such other matters as justice may require.

(3) Limitation on actions

No action may be initiated under this section −

(A) with respect to any act described in subsection (a) of this section that occurred before May 13, 1992, or

(B) more than 6 years after the date when facts material to the act are known or reasonably should have been known by the Secretary but in no event more than 10 years after the date the act took place.

(c) Judicial review

Any person that is the subject of an adverse decision under subsection (b)(1)(A) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

(d) Recovery of penalties

The Attorney General may recover any civil penalty (plus interest

at the currently prevailing rates from the date the penalty became final) assessed under subsection (b)(1)(A) of this section in an action brought in the name of the United States. The amount of such penalty may be deducted, when the penalty has become final, from any sums then or later owing by the United States to the person against whom the penalty has been assessed. In an action brought under this subsection, the validity, amount, and appropriateness of the penalty shall not be subject to judicial review.

(e) Informants

The Secretary may award to any individual (other than an officer or employee of the Federal Government or a person who materially participated in any conduct described in subsection (a) of this section) who provides information leading to the imposition of a civil penalty under this section an amount not to exceed −

(1) $250,000, or

(2) one−half of the penalty so imposed and collected,

whichever is less. The decision of the Secretary on such award shall not be reviewable.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 307, as added Pub. L. 102−282, Sec. 3, May 13, 1992, 106 Stat. 159; amended Pub. L. 103−80, Sec. 3(g), Aug. 13, 1993, 107 Stat. 776.)

−MISC1−

PRIOR PROVISIONS

A prior section 307 of act June 25, 1938, was renumbered section 310 and is classified to section 337 of this title.

AMENDMENTS

1993 − Subsec. (b)(3)(A). Pub. L. 103−80 made technical amendment to reference to May 13, 1992, to reflect correction of corresponding provision of original act.

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102−282, see section 7 of Pub. L. 102−282, set out as a note under section 335a of this title.

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 335a of this title.

−CITE−

21 USC Sec. 335c 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 335c. Authority to withdraw approval of abbreviated drug applications

−STATUTE−

(a) In general

The Secretary −

(1) shall withdraw approval of an abbreviated drug application if the Secretary finds that the approval was obtained, expedited, or otherwise facilitated through bribery, payment of an illegal gratuity, or fraud or material false statement, and

(2) may withdraw approval of an abbreviated drug application if the Secretary finds that the applicant has repeatedly demonstrated a lack of ability to produce the drug for which the application was submitted in accordance with the formulations or manufacturing practice set forth in the abbreviated drug application and has introduced, or attempted to introduce, such adulterated or misbranded drug into commerce.

(b) Procedure

The Secretary may not take any action under subsection (a) of this section with respect to any person unless the Secretary has issued an order for such action made on the record after opportunity for an agency hearing on disputed issues of material fact. In the course of any investigation or hearing under this subsection, the Secretary may administer oaths and affirmations, examine witnesses, receive evidence, and issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence that relates to the matter under investigation.

(c) Applicability

Subsection (a) of this section shall apply with respect to offenses or acts regardless of when such offenses or acts occurred.

(d) Judicial review

Any person that is the subject of an adverse decision under

subsection (a) of this section may obtain a review of such decision by the United States Court of Appeals for the District of Columbia or for the circuit in which the person resides, by filing in such court (within 60 days following the date the person is notified of the Secretary's decision) a petition requesting that the decision be modified or set aside.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 308, as added Pub. L. 102−282, Sec. 4, May 13, 1992, 106 Stat. 160.)

−MISC1−

CONSTRUCTION

This section not to preclude any other civil, criminal, or administrative remedy provided under Federal or State law, including any private right of action against any person for the same action subject to any action or civil penalty under an amendment made by Pub. L. 102−282, see section 7 of Pub. L. 102−282, set out as a note under section 335a of this title.

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 321 of this title.

−CITE−

21 USC Sec. 336 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 336. Report of minor violations

−STATUTE−

Nothing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 309, formerly Sec. 306, 52 Stat. 1045; renumbered Sec. 309, Pub. L. 102−282, Sec. 2, May 13, 1992, 106 Stat. 150.)

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−CITE−

21 USC Sec. 337 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III − PROHIBITED ACTS AND PENALTIES

−HEAD−

Sec. 337. Proceedings in name of United States; provision as to subpoenas

−STATUTE−

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or

has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 310, formerly Sec. 307, 52 Stat. 1046; Sept. 3, 1954, ch. 1263, Sec. 37, 68 Stat. 1239; Pub. L. 101−535, Sec. 4, Nov. 8, 1990, 104 Stat. 2362; renumbered Sec. 310, Pub. L. 102−282, Sec. 2, May 13, 1992, 106 Stat. 150.)

−MISC1−

AMENDMENTS

1990 − Pub. L. 101−535 substituted "(a) Except as provided in subsection (b) of this section, all" for "All" and "any proceeding under this section" for "any such proceeding" and added subsec. (b).

1954 − Act Sept. 3, 1954, struck out reference to section 654 of title 28.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101−535 effective 24 months after Nov. 8, 1990, except that such amendment effective Dec. 31, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances, see section 10(a)(1)(C) of Pub. L. 101−535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101−535

Amendments by Pub. L. 101−535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary

of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101−535, set out as a note under section 343 of this title.

−CITE−

21 USC SUBCHAPTER IV − FOOD 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER IV − FOOD

.

−HEAD−

SUBCHAPTER IV − FOOD

−CITE−

21 USC Sec. 341 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER IV − FOOD

−HEAD−

Sec. 341. Definitions and standards for food

−STATUTE−

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he

shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 401, 52 Stat. 1046; Apr. 15, 1954, ch. 143, Sec. 1, 68 Stat. 54; Aug. 1, 1956, ch. 861, Sec. 1, 70

Stat. 919; Pub. L. 103−80, Sec. 3(h), Aug. 13, 1993, 107 Stat. 776.)

−MISC1−

AMENDMENTS

1993 − Pub. L. 103−80 substituted "or reasonable standards of fill of container. No definition" for "and/or reasonable standards of fill of container: Provided, That no definition".

1956 − Act Aug. 1, 1956, designated provisions constituting subsec. (a) as entire section and repealed subsec. (b) which provided the procedure for establishment of regulations and is covered by section 371(e) of this title.

1954 − Act Apr. 15, 1954, designated existing provisions as subsec. (a) and added subsec. (b).

SAVINGS PROVISION

Section 3 of act Aug. 1, 1956, provided that: "In any case in which, prior to the enactment of this Act (Aug. 1, 1956), a public hearing has been begun in accordance with section 401 of the Federal Food, Drug, and Cosmetic Act (341 of this title) upon a proposal to issue, amend, or repeal any regulation contemplated by such section, or has been begun in accordance with section 701(e) of such Act (section 371(e) of this title) upon a proposal to issue, amend, or repeal any regulation contemplated by section 403(j), 404(a), 406(a) or (b), 501(b), 502(d), 502(h), 504 or 604 of such Act (section 343(j), 344(a), 346(a) or (b), 351(b), 352(d), 352(h), 354, or 364 of this title), the provisions of such section 401 or 701(e), as the case may be, as in force immediately prior to

the date of the enactment of this Act (Aug. 1, 1956), shall be applicable as though this Act (amending this section and section 371(e) of this title) had not been enacted."

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under section 41 of this title.

−MISC5−

FOOD SAFETY AND SECURITY STRATEGY

Pub. L. 107−188, title III, Sec. 301, June 12, 2002, 116 Stat. 662, provided that:

"(a) In General. − The President's Council on Food Safety (as established by Executive Order No. 13100 (set out below)) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

"(b) Authorization of Appropriations. − For the purpose of

implementing the strategy developed under subsection (a), there are authorized to be appropriated $750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year."

FOOD SAFETY COMMISSION

Pub. L. 107−171, title X, Sec. 10807, May 13, 2002, 116 Stat. 527, provided that:

"(a) Establishment. −

"(1) In general. − There is established a commission to be known as the 'Food Safety Commission' (referred to in this section as the 'Commission').

"(2) Membership. −

"(A) Composition. − The Commission shall be composed of 15 members (including a Chairperson, appointed by the President()).

"(B) Eligibility. −

"(i) In general. − Members of the Commission −

"(I) shall have specialized training or significant experience in matters under the jurisdiction of the Commission; and

"(II) shall represent, at a minimum −

"(aa) consumers;

"(bb) food scientists;

"(cc) the food industry; and

"(dd) health professionals.

"(ii) Federal employees. − Not more than 3 members of the Commission may be Federal employees.

"(C) Date of appointments. − The appointment of the members

of the Commission shall be made as soon as practicable after the date on which funds authorized to be appropriated under subsection (e)(1) are made available.

"(D) Vacancies. − A vacancy on the Commission −

"(i) shall not affect the powers of the Commission; and

"(ii) shall be filled −

"(I) not later than 60 days after the date on which the vacancy occurs; and

"(II) in the same manner as the original appointment was made.

"(3) Meetings. −

"(A) Initial meeting. − The initial meeting of the Commission shall be conducted not later than 30 days after the date of appointment of the final member of the Commission.

"(B) Other meetings. − The Commission shall meet at the call of the Chairperson.

"(4) Quorum; standing rules. −

"(A) Quorum. − A majority of the members of the Commission shall constitute a quorum to conduct business.

"(B) Standing rules. − At the first meeting of the Commission, the Commission shall adopt standing rules of the Commission to guide the conduct of business and decisionmaking of the Commission.

"(b) Duties. −

"(1) Recommendations. − The Commission shall make specific recommendations to enhance the food safety system of the United States, including a description of how each recommendation would

improve food safety.

"(2) Components. − Recommendations made by the Commission under paragraph (1) shall address all food available commercially in the United States.

"(3) Report. − Not later than 1 year after the date on which the Commission first meets, the Commission shall submit to the President and Congress −

"(A) the findings, conclusions, and recommendations of the Commission, including a description of how each recommendation would improve food safety;

"(B) a summary of any other material used by the Commission in the preparation of the report under this paragraph; and

"(C) if requested by 1 or more members of the Commission, a statement of the minority views of the Commission.

"(c) Powers of the Commission. −

"(1) Hearings. − The Commission may, for the purpose of carrying out this section, hold such hearings, meet and act at such times and places, take such testimony, and receive such evidence as the Commission considers advisable.

"(2) Information from federal agencies. −

"(A) In general. − The Commission may secure directly, from any Federal agency, such information as the Commission considers necessary to carry out this section.

"(B) Provision of information. −

"(i) In general. − Subject to subparagraph (C), on the request of the Commission, the head of a Federal agency

described in subparagraph (A) may furnish information requested by the Commission to the Commission.

"(ii) Administration. − The furnishing of information by a Federal agency to the Commission shall not be considered a waiver of any exemption available to the agency under section 552 of title 5, United States Code.

"(C) Information to be kept confidential. −

"(i) In general. − For purposes of section 1905 of title 18, United States Code −

"(I) the Commission shall be considered an agency of the Federal Government; and

"(II) any individual employed by an individual, entity, or organization that is a party to a contract with the Commission under this section shall be considered an employee of the Commission.

"(ii) Prohibition on disclosure. − Information obtained by the Commission, other than information that is available to the public, shall not be disclosed to any person in any manner except to an employee of the Commission as described in clause (i), for the purpose of receiving, reviewing, or processing the information.

"(d) Commission Personnel Matters. −

"(1) Members. −

"(A) Compensation. − A member of the Commission shall serve without compensation for the services of the member on the Commission.

"(B) Travel expenses. − A member of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for an employee of an agency under subchapter I of chapter 57 of title 5, United States Code, while away from the home or regular place of business of the member in the performance of the duties of the Commission.

"(2) Staff. −

"(A) In general. − The Chairperson of the Commission may, without regard to the civil service laws (including regulations), appoint and terminate the appointment of an executive director and such other additional personnel as are necessary to enable the Commission to perform the duties of the Commission.

"(B) Confirmation of executive director. − The employment of an executive director shall be subject to confirmation by the Commission.

"(C) Compensation. −

"(i) In general. − Except as provided in clause (ii), the Chairperson of the Commission may fix the compensation of the executive director and other personnel without regard to the provisions of chapter 51 and subchapter III of chapter 53 of title 5, United States Code, relating to classification of positions and General Schedule pay rates.

"(ii) Maximum rate of pay. − The rate of pay for the executive director and other personnel shall not exceed the rate payable for level II of the Executive Schedule under

section 5316 of title 5, United States Code.

"(3) Detail of federal government employees. −

"(A) In general. − An employee of the Federal Government may be detailed to the Commission, without reimbursement, for such period of time as is permitted by law.

"(B) Civil service status. − The detail of the employee shall be without interruption or loss of civil service status or privilege.

"(4) Procurement of temporary and intermittent services. − The Chairperson of the Commission may procure temporary and intermittent services in accordance with section 3109(b) of title 5, United States Code, at rates for individuals that do not exceed the daily equivalent of the annual rate of basic pay prescribed for level II of the Executive Schedule under section 5316 of that title.

"(e) Authorization of Appropriations. −

"(1) In general. − There is authorized to be appropriated such sums as are necessary to carry out this section.

"(2) Limitation. − No payment may be made under subsection (d) except to the extent provided for in advance in an appropriations Act.

"(f) Termination. − The Commission shall terminate on the date that is 60 days after the date on which the Commission submits the recommendations and report under subsection (b)(3)."

−EXEC−

EX. ORD. NO. 13100. PRESIDENT'S COUNCIL ON FOOD SAFETY

Ex. Ord. No. 13100, Aug. 25, 1998, 63 F.R. 45661, as amended by Ex. Ord. No. 13286, Sec. 16, Feb. 28, 2003, 68 F.R. 10623, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to improve the safety of the food supply through science−based regulation and well−coordinated inspection, enforcement, research, and education programs, it is hereby ordered as follows:

Section 1. Establishment of President's Council on Food Safety.

(a) There is established the President's Council on Food Safety ("Council"). The Council shall comprise the Secretaries of Agriculture, Commerce, Health and Human Services, and Homeland Security, the Director of the Office of Management and Budget (OMB), the Administrator of the Environmental Protection Agency, the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy, the Assistant to the President for Domestic Policy, and the Director of the National Partnership for Reinventing Government. The Council shall consult with other Federal agencies and State, local, and tribal government agencies, and consumer, producer, scientific, and industry groups, as appropriate.

(b) The Secretaries of Agriculture and of Health and Human Services and the Assistant to the President for Science and Technology/Director of the Office of Science and Technology Policy shall serve as Joint Chairs of the Council.

Sec. 2. Purpose. The purpose of the Council shall be to develop a

comprehensive strategic plan for Federal food safety activities, taking into consideration the findings and recommendations of the National Academy of Sciences report "Ensuring Safe Food from Production to Consumption" and other input from the public on how to improve the effectiveness of the current food safety system.

The Council shall make recommendations to the President on how to advance Federal efforts to implement a comprehensive science−based strategy to improve the safety of the food supply and to enhance coordination among Federal agencies, State, local, and tribal governments, and the private sector. The Council shall advise Federal agencies in setting priority areas for investment in food safety.

Sec. 3. Specific Activities and Functions. (a) The Council shall develop a comprehensive strategic Federal food safety plan that contains specific recommendations on needed changes, including measurable outcome goals. The principal goal of the plan should be the establishment of a seamless, science−based food safety system. The plan should address the steps necessary to achieve this goal, including the key public health, resource, and management issues regarding food safety. The planning process should consider both short−term and long−term issues including new and emerging threats and the special needs of vulnerable populations such as children and the elderly. In developing this plan, the Council shall consult with all interested parties, including State and local agencies, tribes, consumers, producers, industry, and academia.

(b) Consistent with the comprehensive strategic Federal food

safety plan described in section 3(a) of this order, the Council shall advise agencies of priority areas for investment in food safety and ensure that Federal agencies annually develop coordinated food safety budgets for submission to the OMB that sustain and strengthen existing capacities, eliminate duplication, and ensure the most effective use of resources for improving food safety. The Council shall also ensure that Federal agencies annually develop a unified budget for submission to the OMB for the President's Food Safety Initiative and such other food safety issues as the Council determines appropriate.

(c) The Council shall ensure that the Joint Institute for Food Safety Research (JIFSR), in consultation with the National Science and Technology Council, establishes mechanisms to guide Federal research efforts toward the highest priority food safety needs. The JIFSR shall report to the Council on a regular basis on its efforts: (i) to develop a strategic plan for conducting food safety research activities consistent with the President's Food Safety Initiative and such other food safety activities as the JIFSR determines appropriate; and (ii) to coordinate efficiently, within the executive branch and with the private sector and academia, all Federal food safety research.

Sec. 4. Cooperation. All actions taken by the Council shall, as appropriate, promote partnerships and cooperation with States, tribes, and other public and private sector efforts wherever possible to improve the safety of the food supply.

Sec. 5. General Provisions. This order is intended only to

improve the internal management of the executive branch and is not intended to, nor does it, create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers or any person. Nothing in this order shall affect or alter the statutory responsibilities of any Federal agency charged with food safety responsibilities.

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 337, 343, 343−1, 350, 371 of this title.

−CITE−

21 USC Sec. 342 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER IV − FOOD

−HEAD−

Sec. 342. Adulterated food

−STATUTE−

A food shall be deemed to be adulterated −

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to

health. (FOOTNOTE 1) (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

(FOOTNOTE 1) So in original. The period probably should be "; or".

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 379e(a) of this title.

(d) Confectionery containing alcohol or nonnutritive substance

If it is confectionery, and −

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one−half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced or delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale;

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this chapter, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that −

(A) presents a significant or unreasonable risk of illness or injury under −

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate

information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5 to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

(2) Before the Secretary may report to a United States attorney a violation of paragraph (FOOTNOTE 2) (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(FOOTNOTE 2) So in original. Probably should be "subparagraph".

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 381(a) of this title, unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this chapter, as determined by the Secretary.

−SOURCE−

(June 25, 1938, ch. 675, Sec. 402, 52 Stat. 1046; Mar. 16, 1950, ch. 61, Sec. 3(d), 64 Stat. 21; July 22, 1954, ch. 559, Sec. 2, 68 Stat. 511; July 9, 1956, ch. 530, 70 Stat. 512; Pub. L. 85−929, Sec. 3(a), (b), Sept. 6, 1958, 72 Stat. 1784; Pub. L. 86−2, Mar.

17, 1959, 73 Stat. 3; Pub. L. 86−618, title I, Sec. 102(a)(1), (2), 105(c), July 12, 1960, 74 Stat. 397, 398, 404; Pub. L. 89−477, June 29, 1966, 80 Stat. 231; Pub. L. 90−399, Sec. 104, July 13, 1968, 82 Stat. 352; Pub. L. 99−252, Sec. 10, Feb. 27, 1986, 100 Stat. 35; Pub. L. 102−571, title I, Sec. 107(4), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 103−80, Sec. 3(i), Aug. 13, 1993, 107 Stat. 776; Pub. L. 103−417, Sec. 4, 9, Oct. 25, 1994, 108 Stat. 4328, 4332; Pub. L. 104−170, title IV, Sec. 404, Aug. 3, 1996, 110 Stat. 1514; Pub. L. 107−188, title III, Sec. 309, June 12, 2002, 116 Stat. 673.)

−MISC1−

AMENDMENTS

2002 − Subsec. (h). Pub. L. 107−188 added subsec. (h).

1996 − Par. (a). Pub. L. 104−170 added subpar. (2) and struck out former subpar. (2) which read as follows: "(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or if it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title

and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title;". That part of Pub. L. 104−170 which directed the substitution of "or (3) if it consists" for "(3) if it consists" was executed by making the substitution for "(3) If it consists" to reflect the probable intent of Congress.

1994 − Par. (f). Pub. L. 103−417, Sec. 4, added par. (f).

Par. (g). Pub. L. 103−417, Sec. 9, added par. (g).

1993 − Par. (a). Pub. L. 103−80, Sec. 3(i)(1), substituted a period for "; or" at end of subpar. (1) and "If it" for "if it" at beginning of par. (3). That part of Pub. L. 103−80, Sec. 3(i)(1), which directed the substitution of a period for "; or" at end of subpar. (2) could not be executed because "; or" did not appear.

Par. (d)(1). Pub. L. 103−80, Sec. 3(i)(2), substituted ", except that this subparagraph" for ": Provided, That this clause".

Par. (d)(3). Pub. L. 103−80, Sec. 3(i)(3), substituted ", except that this subparagraph shall not apply" for ": Provided, That this clause shall not apply" and ", except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph" for ": And provided further, That the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this clause".

1992 − Par. (c). Pub. L. 102−571 substituted "379e(a)" for "376(a)".

1986 − Par. (d)(2). Pub. L. 99−252 inserted provision that this clause not apply to confectionery introduced or delivered for introduction into or received or held for sale in, interstate commerce if the sale is permitted under the laws of the State in which the confectionery is intended to be offered for sale.

1968 − Par. (a)(2). Pub. L. 90−399 added cls. (A)(iv) and (D).

1966 − Par. (d). Pub. L. 89−477 permitted the imbedding of nonnutritive objects in confectionery foods if in the judgment of the Secretary of Health, Education, and Welfare, as provided by regulation, the imbedding of the object is of practical functional value to the confectionery product and would not render it injurious or hazardous to health, raised to one−half of 1 per centum by volume the upper limit for the allowable use of alcohol derived solely from the use of flavoring extracts, allowed the use of safe nonnutritive substances in and on confectionery foods by reason of their use for some practical and functional purpose in the manufacture, packaging, or storage of the confectionery foods

if the use of the substances does not promote deception of the consumer or otherwise result in adulteration or misbranding, authorized the Secretary to issue regulations on the use of particular nonnutritive substances, and removed reference to nonnutritive masticatory substances added to chewing gum and harmless flavoring, harmless resinous glaze not in excess of four−tenths of 1 per centum, natural gum, authorized coloring, and pectin.

1960 − Par. (a). Pub. L. 86−618, Sec. 102(a)(1), substituted "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive" for "(except a pesticide chemical in or on a raw agricultural commodity and except a food additive)" in cl. (2)(A).

Par. (c). Pub. L. 86−618, Sec. 102(a)(2), amended par. (c) generally, substituting provisions deeming a food adulterated if it is, or it bears or contains, a color additive which is unsafe within the meaning of section 376 of this title for provisions which related to food that bears or contains a coal−tar color other than one from a batch that has been certified in accordance with regulations as provided by section 346 of this title, and struck out provisos which related to the use of color on oranges.

Par. (d). Pub. L. 86−618, Sec. 105(c), substituted "authorized coloring" for "harmless coloring".

1959 − Par. (c). Pub. L. 86−2 extended from Mar. 1, 1959, to May 1, 1959, the period during which subsection is inapplicable to oranges which have been colored with F.D. & C. Red 32, and inserted

proviso requiring Secretary to establish regulations prescribing the conditions under which Citrus Red No. 2 may be safely used in coloring certain mature oranges, and providing for separately listing and for certification of batches of such color.

1958 − Par. (a). Pub. L. 85−929, among other changes, inserted cl. (2)(C) relating to food additive unsafe within the meaning of section 348 of this title, and to pesticide chemical, and added cl. (7) relating to radiated food.

1956 − Par. (c). Act July 9, 1956, inserted second proviso relating to coloring of oranges.

1954 − Par. (a)(2). Act July 22, 1954, provided in the case of any raw agricultural commodity bearing or containing a pesticide chemical, that such commodity shall be deemed to be adulterated if such pesticide chemical is unsafe within the meaning of section 346a of this title.

1950 − Par. (e). Act Mar. 16, 1950, added par. (e).

EFFECTIVE DATE OF 1968 AMENDMENT

Amendment by Pub. L. 90−399 effective on first day of thirteenth calendar month after July 13, 1968, see section 108(a) of Pub. L. 90−399, set out as an Effective Date and Transitional Provisions note under section 360b of this title.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86−618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86−618, see section 202 of Pub. L. 86−618, set out as a note under section 379e of this title.

EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND

DESICCANT AMENDMENT OF 1959

Effective date of par. (a)(2) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 3(b) of Pub. L. 86−139, Aug. 7, 1959, 73 Stat. 288.

EFFECTIVE DATE OF 1958 AMENDMENT

Section 6 of Pub. L. 85−929, as amended by Pub. L. 87−19, Sec. 2, Apr. 7, 1961, 75 Stat. 42; Pub. L. 88−625, Sec. 2, Oct. 3, 1964, 78 Stat. 1002, provided that:

"(a) Except as provided in subsections (b) and (c) of this section, this Act (amending this section, sections 321, 331, 346, and 348 of this title, and section 210 of Title 42, The Public Health and Welfare, and enacting provisions set out as notes under sections 321 and 451 of this title) shall take effect on the date of its enactment (Sept. 6, 1958).

"(b) Except as provided in subsection (c) of this section, section 3 of this Act (amending this section and section 346 of this title) shall take effect on the one hundred and eightieth day after the date of enactment of this Act (Sept. 6, 1958).

"(c) With respect to any particular commercial use of a food additive, if such use was made of such additive before January 1, 1958, section 3 of this Act (amending this section and section 346 of this title) shall take effect −

"(1) Either (A) one year after the effective date established in subsection (b) of this section, or (B) at the end of such

additional period (but not later than two years from such effective date established in subsection (b)) as the Secretary of Health, Education, and Welfare (now Health and Human Services) may prescribe on the basis of a finding that such extension involves no undue risk to the public health and that conditions exist which necessitate the prescribing of such an additional period, or

"(2) on the date on which an order with respect to such use under section 409 of the Federal Food, Drug, and Cosmetic Act (section 348 of this title) becomes effective,

whichever date first occurs. Whenever the Secretary has, pursuant to clause (1)(B) of this subsection, extended the effective date of section 3 of this Act (amending this section) to March 5, 1961, or has on that date a request for such extension pending before him, with respect to any such particular use of a food additive, he may, notwithstanding the parenthetical time limitation in that clause, further extend such effective date, not beyond June 30, 1964, under the authority of that clause (but subject to clause (2)) with respect to such use of the additive (or a more limited specified use or uses thereof) if, in addition to making the findings required by clause (1)(B), he finds (i) that bona fide action to determine the applicability of such section 409 (section 348 of this title) to such use or uses, or to develop the scientific data necessary for action under such section, was commenced by an interested person before March 6, 1960, and was thereafter pursued with reasonable diligence, and (ii) that in the Secretary's

judgment such extension is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary as a basis for action under such section 409 (section 348 of this title): Provided, That if the Secretary has, pursuant to this sentence, granted an extension to June 30, 1964, he may, upon making the findings required by clause (1)(B) of this subsection and clauses (i) and (ii) of this sentence, further extend such effective date, but not beyond December 31, 1965. The Secretary may at any time terminate an extension so granted if he finds that it should not have been granted, or that by reason of a change in circumstances the basis for such extension no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such extension."

EFFECTIVE DATE OF 1954 AMENDMENT

Section 5 of act July 22, 1954, provided that: "This Act (amending this section and section 321 of this title and enacting sections 346a and 346b of this title) shall take effect upon the date of its enactment (July 22, 1954), except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act (section 346a of this title), the amendment to section 402(a) of such Act (par. (a) of this section) made by section 2 of this Act shall not be effective −

"(1) for the period of one year following the date of the

enactment of this Act (July 22, 1954); or

"(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act (July 22, 1954) as the Secretary of Health, Education, and Welfare (now Health and Human Services) may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period."

EFFECTIVE DATE OF 1950 AMENDMENT

Amendment by act Mar. 16, 1950, effective July 1, 1950, see section 7 of act Mar. 16, 1950, set out as an Effective Date note under section 347 of this title.

EFFECTIVE DATE; POSTPONEMENT

Par. (c) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 of this title.

SHORT TITLE

Pub. L. 88−625, Sec. 1, Oct. 3, 1964, 78 Stat. 1002, provided:

"That this Act (amending provisions set out as a note under this section and section 135 of Title 7, Agriculture) may be cited as the 'Food Additives Transitional Provisions Amendment of 1964'."

−TRANS−

TRANSFER OF FUNCTIONS

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare (now Health and Human Services), and of Food and Drug Administration in the Department of Agriculture to Federal Security Agency, see note set out under

section 41 of this title.

−MISC5−

DOMESTIC FISH OR FISH PRODUCT COMPLIANCE WITH FOOD SAFETY STANDARDS OR PROCEDURES DEEMED TO HAVE MET REQUIREMENTS FOR FEDERAL COMMODITY PURCHASE PROGRAMS

Pub. L. 104−180, title VII, Sec. 733, Aug. 6, 1996, 110 Stat. 1601, provided that: "Hereafter, notwithstanding any other provision of law, any domestic fish or fish product produced in compliance with food safety standards or procedures accepted by the Food and Drug Administration as satisfying the requirements of the 'Procedures for the Safe and Sanitary Processing and Importing of Fish and Fish Products' (published by the Food and Drug Administration as a final regulation in the Federal Register of December 18, 1995), shall be deemed to have met any inspection requirements of the Department of Agriculture or other Federal agency for any Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c) except that the Department of Agriculture or other Federal agency may utilize lot inspection to establish a reasonable degree of certainty that fish or fish products purchased under a Federal commodity purchase program, including the program authorized under section 32 of the Act of August 24, 1935 (7 U.S.C. 612c), meet Federal product specifications."

−SECREF−

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 346, 346a,

346b, 347b, 348, 350a, 350b, 360b, 379e of this title.

−CITE−

21 USC Sec. 343 01/06/03

−EXPCITE−

TITLE 21 − FOOD AND DRUGS

CHAPTER 9 − FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER IV − FOOD

−HEAD−

Sec. 343. Misbranded food

−STATUTE−

A food shall be deemed to be misbranded −

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or

(2) in the case of a food to which section 350 of this title

applies, its advertising is false or misleading in a material

respect or its labeling is in violation of section 350(b)(2) of

this title.

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in

type of uniform size and prominence, the word "imitation" and,

immediately thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to be

misleading.

(e) Package form

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) Representation as to definition and standard of identity

If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341 of this title, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) Representation as to standards of quality and fill of container

If it purports to be or is represented as −

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 341 of this title, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 341 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(3) a food that is pasteurized unless −

(A) such food has been subjected to a safe process or treatment that is prescribed as pasteurization for such food in a regulation promulgated under this chapter; or

(B)(i) such food has been subjected to a safe process or treatment that −

(I) is reasonably certain to achieve destruction or elimination in the food of the most resistant microorganisms of public health significance that are likely to occur in the food;

(II) is at least as protective of the public health as a process or treatment described in subparagraph (A);

(III) is effective for a period that is at least as long as the shelf life of the food when stored under normal and

moderate abuse conditions; and

(IV) is the subject of a notification to the Secretary, including effectiveness data regarding the process or treatment; and

(ii) at least 120 days have passed after the date of receipt of such notification by the Secretary without the Secretary making a determination that the process or treatment involved has not been shown to meet the requirements of subclauses (I) through (III) of clause (i).

For purposes of paragraph (3), a determination by the Secretary that a process or treatment has not been shown to meet the requirements of subclauses (I) through (III) of subparagraph (B)(i) shall constitute final agency action under such subclauses.

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title (FOOTNOTE 1) unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of

clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(FOOTNOTE 1) So in original. Probably should be followed by a comma.

(j) Representation for special dietary use

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) Artificial flavoring, artificial coloring, or chemical preservatives

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) Pesticide chemicals on raw agricultural commodities

If it is a raw agricultural commodity which is the produce of the

soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) Color additives

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 379e of this title.

(n) Packaging or labeling of drugs in violation of regulations

If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of title 15.

(o) Repealed. Pub. L. 106−554, Sec. 1(a)(1) (title V, Sec. 517), Dec. 21, 2000, 114 Stat. 2763, 2763A−73

(p) Repealed. Pub. L. 104−124, Sec. 1, Apr. 1, 1996, 110 Stat. 882

(q) Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides −

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is

appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories −

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a

nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to subparagraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by subparagraph (1)(C), (1)(D), or (1)(E) or clause (A) of this subparagraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by subparagraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by subparagraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by clause (B) or by issuing regulations that are mandatory as provided by clause (D).

(B)(i) Upon the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall

issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in subparagraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12−month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply −

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under subclause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial−compliance standard has been met.

(C)(i) Upon the expiration of 30 months after November 8, 1990,

the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under clause (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in subclause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under clause (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by subparagraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under subclause (i) may require that the nutrition information required by subparagraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in

which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by subparagraphs (1) and (2).

(iii) Regulations issued under subclause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this subparagraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this subparagraph if there has been substantial compliance with the requirements of this paragraph.

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food −

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 350a of this title,

(iv) which is a medical food as defined in section 360ee(b) of this title, or

(v) which is described in section 345(2) of this title.

(B) Subparagraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such subparagraphs is impracticable because the package of such food is too small to comply with the requirements of such subparagraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by subparagraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such subparagraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a

food contains insignificant amounts, as determined by the Secretary, of more than one−half the nutrients required by subparagraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of subparagraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E)(i) During the 12−month period for which an exemption from subparagraphs (1) and (2) is claimed pursuant to this subclause, the requirements of such subparagraphs shall not apply to any food product if −

(I) the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r),

(II) the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 100 full−time equivalent employees,

(III) such person provided the notice described in subclause (iii), and

(IV) in the case of a food product which was sold in the 12−month period preceding the period for which an exemption was

claimed, fewer than 100,000 units of such product were sold in the United States during such preceding period, or in the case of a food product which was not sold in the 12−month period preceding the period for which such exemption is claimed, fewer than 100,000 units of such product are reasonably anticipated to be sold in the United States during the period for which such exemption is claimed.

(ii) During the 12−month period after the applicable date referred to in this sentence, the requirements of subparagraphs (1) and (2) shall not apply to any food product which was first introduced into interstate commerce before May 8, 1994, if the labeling for such product does not provide nutrition information or make a claim subject to paragraph (r), if such person provided the notice described in subclause (iii), and if −

(I) during the 12−month period preceding May 8, 1994, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full−time equivalent employees and fewer than 600,000 units of such product were sold in the United States,

(II) during the 12−month period preceding May 8, 1995, the person who claims for such product an exemption from such subparagraphs employed fewer than an average of 300 full−time equivalent employees and fewer than 400,000 units of such product were sold in the United States, or

(III) during the 12−month period preceding May 8, 1996, the person who claims for such product an exemption from such

subparagraphs employed fewer than an average of 200 full−time equivalent employees and fewer than 200,000 units of such product were sold in the United States.

(iii) The notice referred to in subclauses (i) and (ii) shall be given to the Secretary prior to the beginning of the period during which the exemption under subclause (i) or (ii) is to be in effect, shall state that the person claiming such exemption for a food product has complied with the applicable requirements of subclause (i) or (ii), and shall −

(I) state the average number of full−time equivalent employees such person employed during the 12 months preceding the date such person claims such exemption,

(II) state the approximate number of units the person claiming the exemption sold in the United States,

(III) if the exemption is claimed for a food product which was sold in the 12−month period preceding the period for which the exemption was claimed, state the approximate number of units of such product which were sold in the United States during such preceding period, and, if the exemption is claimed for a food product which was not sold in such preceding period, state the number of units of such product which such person reasonably anticipates will be sold in the United States during the period for which the exemption was claimed, and

(IV) contain such information as the Secretary may require to verify the information required by the preceding provisions of this subclause if the Secretary has questioned the validity of

such information.

If a person is not an importer, has fewer than 10 full−time equivalent employees, and sells fewer than 10,000 units of any food product in any year, such person is not required to file a notice for such product under this subclause for such year.

(iv) In the case of a person who claimed an exemption under subclause (i) or (ii), if, during the period of such exemption, the number of full−time equivalent employees of such person exceeds the number in such subclause or if the number of food products sold in the United States exceeds the number in such subclause, such exemption shall extend to the expiration of 18 months after the date the number of full−time equivalent employees or food products sold exceeded the applicable number.

(v) For any food product first introduced into interstate commerce after May 8, 2002, the Secretary may by regulation lower the employee or units of food products requirement of subclause (i) if the Secretary determines that the cost of compliance with such lower requirement will not place an undue burden on persons subject to such lower requirement.

(vi) For purposes of subclauses (i), (ii), (iii), (iv), and (v) −

(I) the term "unit" means the packaging or, if there is no packaging, the form in which a food product is offered for sale to consumers,

(II) the term "food product" means food in any sized package which is manufactured by a single manufacturer or which bears the same brand name, which bears the same statement of identity, and

which has similar preparation methods, and

(III) the term "person" in the case of a corporation includes all domestic and foreign affiliates of the corporation.

(F) A dietary supplement product (including a food to which section 350 of this title applies) shall comply with the requirements of subparagraphs (1) and (2) in a manner which is appropriate for the product and which is specified in regulations of the Secretary which shall provide that −

(i) nutrition information shall first list those dietary ingredients that are present in the product in a significant amount and for which a recommendation for daily consumption has been established by the Secretary, except that a dietary ingredient shall not be required to be listed if it is not present in a significant amount, and shall list any other dietary ingredient present and identified as having no such recommendation;

(ii) the listing of dietary ingredients shall include the quantity of each such ingredient (or of a proprietary blend of such ingredients) per serving;

(iii) the listing of dietary ingredients may include the source of a dietary ingredient; and

(iv) the nutrition information shall immediately precede the ingredient information required under subclause (i), except that no ingredient identified pursuant to subclause (i) shall be required to be identified a second time.

(G) Subparagraphs (1), (2), (3), and (4) shall not apply to food

which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(r) Nutrition levels and health−related claims

(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication −

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food to a disease or a health−related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A) −

(i) may be made only if the characterization of the level made

in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless −

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless −

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one−half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one−half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one−half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health−related condition that is diet related, the label or labeling of such food shall contain, prominently and in

immediate proximity to such claim, the following statement: "See nutrition information for _ _ _ content." The blank shall identify the nutrient associated with the increased disease or health−related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.

(C) Subparagraph (2)(A) does not apply to a claim described in subparagraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under subparagraph (2)(A)(i). Such a claim is subject to paragraph (a).

(D) Subparagraph (2) does not apply to a claim described in subparagraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to paragraph (a).

(E) Subclauses (i) through (v) of subparagraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(F) Subclause (i) clause (A) does not apply to a statement in the labeling of a dietary supplement that characterizes the percentage level of a dietary ingredient for which the Secretary has not established a reference daily intake, daily recommended value, or other recommendation for daily consumption.

(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if −

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been

satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 321(n) of this title; and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(H) A claim submitted under the requirements of clause (G) may be made until −

(i) such time as the Secretary issues a regulation −

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not

submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under subchapter III of this chapter has determined that the requirements of clause (G) have not been met.

(3)(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made −

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health−related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well−designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is

supported by such evidence.

(ii) A regulation described in subclause (i) shall describe −

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease or health−related condition, and

(II) the significance of each such nutrient in affecting such disease or health−related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if −

(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health−related condition to which the claim

refers;

(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health−related condition to which the claim refers;

(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 321(n) of this title; and

(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause

(i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

(D) A claim submitted under the requirements of clause (C) may be made until −

(i) such time as the Secretary issues a regulation under the standard in clause (B)(i) −

(I) prohibiting or modifying the claim and the regulation has become effective, or

(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

(ii) a district court of the United States in an enforcement proceeding under subchapter III of this chapter has determined that the requirements of clause (C) have not been met.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under subparagraph (2)(A)(i) or (3)(B) relating to a claim described in subparagraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary denies the petition or the petition is deemed to be denied, the petition shall not be made available to the public. If the Secretary files the petition,

the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision. If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.

(ii) Any person may petition the Secretary for permission to use in a claim described in subparagraph (1)(A) terms that are consistent with the terms defined by the Secretary under subparagraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in subparagraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under subparagraph (2)(A)(i).

The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under clause (A)(i) respecting a claim described in subparagraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this paragraph and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under subparagraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This paragraph does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar

nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if −

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well−being from consumption of a nutrient or dietary ingredient,

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.".

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after

the first marketing of the dietary supplement with such statement that such a statement is being made.

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary −

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to −

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) Dietary supplements

If −

(1) it is a dietary supplement; and

(2)(A) the label or labeling of the supplement fails to list −

(i) the name of each ingredient of the supplement that is described in section 321(ff) of this title; and

(ii)(I) the quantity of each such ingredient; or

(II) with respect to a proprietary blend of such ingredients,

the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to

identify the product by using the term "dietary supplement",

which term may be modified with the name of such an ingredient;

(C) the supplement contains an ingredient described in section

321(ff)(1)(C) of this title, and the label or labeling of the

supplement fails to identify any part of the plant from which the

ingredient is derived;

(D) the supplement −

(i) is covered by the specifications of an official

compendium;

(ii) is represented as conforming to the specifications of an

official compendium; and

(iii) fails to so conform; or

(E) the supplement −

(i) is not covered by the specifications of an official

compendium; and

(ii)(I) fails to have the identity and strength that the

supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule

disintegration), purity, or compositional specifications, based

on validated assay or other appropriate methods, that the

supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because

its label or labeling contains directions or conditions of use or warnings.

(t) Catfish

If it purports to be or is represented as catfish, unless it is fish classified within the family Ictaluridae.

(u) Ginseng

If it purports to be or is represented as ginseng, unless it is an herb or herbal ingredient derived from a plant classified within the genus Panax.

(v) Failure to label; health threat

If −

(1) it fails to bear a label required by the Secretary under section 381(n)(1) of this title (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner or consignee involved that the label is required under section 381 of this title, the Secretary informs the owner or consignee that the food presents such a threat.