-CITE-

21 USC Sec. 301 01/16/96

-EXPCITE-

TITLE 21 - FOOD AND DRUGS
CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER I - SHORT TITLE

-HEAD-

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 Jue 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 fore 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 drus:', 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 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'."