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.''

DEFINITIONS

Pub. L. 105–115, § 2, Nov. 21, 1997, 111 Stat. 2297, 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).''

Executive Documents

TRANSFER OF FUNCTIONS

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.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out in the Appendix to Title 5, Government Organization and Employees. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Food and Drug Administration in Department of Agriculture and its functions, except those functions relating to administration of Insecticide Act of 1910 and Naval Stores Act, transferred to Federal Security Agency, to be administered under direction and supervision of Federal Security Administrator, by Reorg. Plan No. IV of 1940, set out in the Appendix to Title 5.

§ 321a. "Butter" defined

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.

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

Editorial Notes

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, which was classified to subchapter I (§ 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, § 1002(a), formerly § 902(a), 52 Stat. 1059; renumbered § 1002(a), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784, and is covered by this chapter.

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 1002(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.

§ 321b. "Package" defined

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.

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

Editorial Notes

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 (§ 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, § 1002(a), formerly § 902(a), 52 Stat. 1059; renumbered § 1002(a), Pub. L. 111–31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784, and is covered by this chapter.

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 1002(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.

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

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 1½ per centum by weight unless otherwise indicated.

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

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

Editorial Notes

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 (§ 301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

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.

AMENDMENTS

1956—Act July 2, 1956, substituted ''nonfat dry milk'' for ''nonfat dry milk solids or defatted milk solids''.

§ 321d. Market names for catfish and ginseng

(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

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

Editorial Notes

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.

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.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, 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, 350d, 355, or 360bbb–3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350c, 350f(j), 350e, 354, 360bbb–3, 373, 374(a), 379aa, or 379aa–1 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 350c(b), 350f, 350e, 354, 355(i) or (k), 360b(a)(4)(C), 360b(j), (*l*) or (m), 360ccc–1(i), 360e(f), 360i, 360bbb–3, 379aa, 379aa–1, 387i, or 387t of this title or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 2223[1] of this title (except when such violation is committed by a farm).

(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, tobacco product, 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, tobacco product, 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, 360ccc, 360ccc–1, 360ccc–2, 374, 379, 379e, 387d, 387e, 387f, 387g, 387h, 387i, or 387t(b) of this title concerning any method or process which as a

[1] See References in Text note below.