

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 of chapter 1 of this title, was repealed (except for section 14a which was transferred to section 376 of this title) by act June 25, 1938, ch. 675, §902(a), 52 Stat. 1059, and is covered by this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

§ 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.)

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".

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER REFERRED TO IN OTHER SECTIONS

This subchapter is referred to in section 378 of this title; title 15 section 1456.

§ 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, 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 or 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 355(i) or (k), 357(d) or (g), 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, 356, 357, 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, 355, 356, 357, 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. 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.

(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) The using, on the labeling of any drug or device or in any advertising relating to such drug or device, of any representation or sugges-

tion 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.

(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.

(u)¹ The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title.

(June 25, 1938, ch. 675, §301, 52 Stat. 1042; Dec. 22, 1941, ch. 613, §1, 55 Stat. 851; July 6, 1945, ch. 281, §1, 59 Stat. 463; Mar. 10, 1947, ch. 16, §1, 61 Stat. 11; June 24, 1948, ch. 613, §1, 62 Stat. 582; Mar. 16, 1950, ch. 61, §3(b), 64 Stat. 20; Aug. 7, 1953, ch. 350, §2, 67 Stat. 477; Sept. 6, 1958, Pub. L. 85-929, §5, 72 Stat. 1788; July 12, 1960, Pub. L. 86-618, title I, §§104, 105(a), 74 Stat. 403; Oct. 10, 1962, Pub. L. 87-781, title I, §§103(c), 104(e)(1), 106(c), 114(a), title III, §304, 76 Stat. 784, 785, 788, 791, 795; July 15, 1965, Pub. L. 89-74, §§5, 9(c), 79 Stat. 232, 235; July 13, 1968, Pub. L. 90-399, §103, 82 Stat. 352; Oct. 24, 1968, Pub. L. 90-639, §2(b), 82 Stat. 1361; Oct. 27, 1970, Pub. L. 91-513, title II, §701(a), 84 Stat. 1281; Aug. 16, 1972, Pub. L. 92-387, §4(e), 86 Stat. 562; May 28, 1976, Pub. L. 94-295, §§3(b), 4(b)(1), 7(b), 90 Stat. 576, 580, 582; Sept. 26, 1980, Pub. L. 96-359, §5, 94 Stat. 1193; Oct. 27, 1986, Pub. L. 99-570, title IV, §4014(b)(2), 100 Stat. 3207-120; Apr. 22, 1988, Pub. L. 100-293, §7(a), 102 Stat. 99; Nov. 3, 1990, Pub. L. 101-502, §5(j), 104 Stat. 1289; Nov. 5, 1990, Pub. L. 101-508, title IV, §4755(c)(2), 104 Stat. 1388-210; June 16, 1992, Pub. L. 102-300, §3(a)(1), 106 Stat. 238; Oct. 29, 1992, Pub. L. 102-571, title I, §107(2), (3), 106 Stat. 4499; Aug. 13, 1993, Pub. L. 103-80, §3(c), 107 Stat. 775; Oct. 22, 1994, Pub. L. 103-396, §2(b)(1), 108 Stat. 4154; Oct. 25, 1994, Pub. L. 103-417, §10(b), 108 Stat. 4332.)

AMENDMENTS

1994—Par. (e). Pub. L. 103-396, §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, §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, §3(c)(1), substituted “379, or 379e” for “379e, or 379”.

Par. (s). Pub. L. 103-80, §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).”

¹ So in original. Probably should be “(v)”.

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

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

Par. (s). Pub. L. 96-359, §5(a), added par. (s).

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

Par. (j). Pub. L. 94-295, §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, §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, §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, §3(b)(1), added par. (q).

Par. (r). Pub. L. 94-295, §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, §103(1), inserted reference to section 360b(j), (l), and (m) of this title.

Par. (j). Pub. L. 90-399, §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, §9(c), designated existing provisions as subpar. (1) and added subpars. (2) and (3).

Par. (q). Pub. L. 89-74, §5, added par. (q).

1962—Par. (e). Pub. L. 87-781, §§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, §104(e)(1), inserted “approval of” before “an application”, and substituted “in effect” for “effective”.

Par. (o). Pub. L. 87-781, §114(a), added par. (o).

Par. (p). Pub. L. 87-781, §304, added par. (p).

1960—Par. (i). Pub. L. 86-618, §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, §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 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 in-

cluded in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, title VI, §§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.

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 ac-

cord 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.

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.

SECTION REFERRED TO IN OTHER SECTIONS

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

§ 332. Injunction proceedings

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown¹ to restrain violations of section 331 of this title, except paragraphs (h), (i), and (j).

(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.

(June 25, 1938, ch. 675, § 302, 52 Stat. 1043; Oct. 10, 1962, Pub. L. 87-781, title I, § 103(d), title II, § 201(c), 76 Stat. 784, 793; Aug. 13, 1993, Pub. L. 103-80, § 3(d), 107 Stat. 775.)

AMENDMENTS

1993—Subsec. (a). Pub. L. 103-80, § 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, § 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, § 103(d), struck out “(e),” after “paragraphs”.

Pub. L. 87-781, § 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].”

SECTION REFERRED TO IN OTHER SECTIONS

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

§ 333. Penalties

(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,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.

(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 manufac-

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

¹ So in original. Words “of this section” probably should not appear.