SUBCHAPTER I—SHORT TITLE

§ 301. Short title

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

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

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE; POSTPONEMENT IN CERTAIN CASES

Act June 23, 1939, ch. 242, §§ 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

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, 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.''

SHORT TITLE OF 2023 AMENDMENT

Pub. L. 118–15, div. B, title III, § 2301(a), Sept. 30, 2023, 137 Stat. 86, provided that: ''This chapter [chapter 1 (§§ 2301–2307) of subtitle A of title III of div. B of Pub. L. 118–15, amending sections 379j–11 to 379j–13 of this title, enacting provisions set out as notes under sections 379j–11 to 379j–13 of this title, and repealing provisions set out as notes under sections 379j–12 and 379j–13 of this title] may be cited as the 'Animal Drug User Fee Amendments of 2023'.''

Pub. L. 118–15, div. B, title III, § 2311(a), Sept. 30, 2023, 137 Stat. 90, provided that: ''This chapter [chapter 2 (§§ 2311–2316) of subtitle A of title III of div. B of Pub. L. 118–15, amending sections 379j–21 and 379j–22 of this title, enacting provisions set out as notes under sections 379j–21 and 379j–22 of this title, and repealing provisions set out as notes under sections 379j–21 and 379j–22 of this title] may be cited as the 'Animal Generic Drug User Fee Amendments of 2023'.''

SHORT TITLE OF 2022 AMENDMENT

Pub. L. 117–328, div. FF, title III, § 3001, Dec. 29, 2022, 136 Stat. 5807, provided that: ''This title [see Tables for

classification] may be cited as the 'Food and Drug Omnibus Reform Act of 2022'.''

Pub. L. 117–328, div. FF, title III, § 3501, Dec. 29, 2022, 136 Stat. 5847, provided that: ''This subtitle [subtitle E (§§ 3501–3508), enacting sections 364 to 364j of this title, amending sections 331, 361, 362, 374, and 381 of this title, and enacting provisions set out as notes under sections 331, 364, 364d, and 364e of this title] may be cited as the 'Modernization of Cosmetics Regulation Act of 2022'.''

Pub. L. 117–180, div. F, § 1, Sept. 30, 2022, 136 Stat. 2139, provided that: ''This division [see Tables for classification] may be cited as the 'FDA User Fee Reauthorization Act of 2022'.''

Pub. L. 117–180, div. F, title I, § 1001(a), Sept. 30, 2022, 136 Stat. 2140, provided that: ''This title [amending sections 379g, 379h, and 379h–2 of this title, enacting notes set out under sections 379g and 379h–2 of this title, and repealing notes set out under sections 379g and 379h–2 of this title] may be cited as the 'Prescription Drug User Fee Amendments of 2022'.''

Pub. L. 117–180, div. F, title II, § 2001(a), Sept. 30, 2022, 136 Stat. 2147, provided that: ''This title [amending sections 360d, 360m, and 379i to 379j–1 of this title, enacting notes set out under sections 360d, 379i, and 379j–1 of this title, and repealing provisions set out as notes under sections 379i and 379j–1 of this title] may be cited as the 'Medical Device User Fee Amendments of 2022'.''

Pub. L. 117–180, div. F, title III, § 3001(a), Sept. 30, 2022, 136 Stat. 2155, provided that: ''This title [amending sections 379j–42 and 379j–43 of this title, enacting provisions set out as notes under sections 379j–41 and 379j–43 of this title, and repealing provisions set out as notes under sections 379j–41 and 379j–43 of this title] may be cited as the 'Generic Drug User Fee Amendments of 2022'.''

Pub. L. 117–180, div. F, title IV, § 4001(a), Sept. 30, 2022, 136 Stat. 2160, provided that: ''This title [amending sections 379j–51 to 379j–53 of this title, enacting provisions set out as notes under sections 379j–51 and 379j–53 of this title, and repealing provisions set out as notes under sections 379j–51 and 379j–53 of this title] may be cited as the 'Biosimilar User Fee Amendments of 2022'.''

Pub. L. 117–101, § 1, Mar. 15, 2022, 136 Stat. 47, provided that: ''This Act [amending section 379dd of this title and section 290b of Title 42, The Public Health and Welfare] may be cited as the 'Supporting the Foundation for the National Institutes of Health and the Reagan-Udall Foundation for the Food and Drug Administration Act'.''

Short Title of 2021 Amendment

Pub. L. 117–79, § 1, Dec. 23, 2021, 135 Stat. 1533, provided that: ''This Act [enacting section 360ee–1 of this title, section 280g–7b of Title 42, The Public Health and Welfare, and provisions set out as notes under sections 360aa and 360ee of this title] may be cited as the 'Accelerating Access to Critical Therapies for ALS Act'.''

Pub. L. 117–11, § 1, Apr. 23, 2021, 135 Stat. 262, provided that: ''This Act [amending section 321 of this title and enacting provisions set out as a note under section 321 of this title] may be cited as the 'Food Allergy Safety, Treatment, Education, and Research Act of 2021' or the 'FASTER Act of 2021'.''

Pub. L. 116–304, § 1, Jan. 5, 2021, 134 Stat. 4915, provided that: ''This Act [amending sections 321 and 381 of this title] may be cited as the 'Safeguarding Therapeutics Act'.''

Pub. L. 116–290, § 1, Jan. 5, 2021, 134 Stat. 4889, provided that: ''This Act [amending section 355 of this title and enacting provisions set out as a note under section 355 of this title] may be cited as the 'Orange Book Transparency Act of 2020'.''

Short Title of 2018 Amendment

Pub. L. 115–271, § 1(a), Oct. 24, 2018, 132 Stat. 3894, provided that: ''This Act [see Tables for classification] may be cited as the 'Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act' or the 'SUPPORT for Patients and Communities Act'.''

Pub. L. 115–271, title III, § 3011, Oct. 24, 2018, 132 Stat. 3935, provided that: ''This chapter [chapter 2 (§§ 3011–3014) of subtitle A of title III of Pub. L. 115–271, enacting sections 360bbb–8d and 384f of this title, amending sections 331 and 381 of this title, and enacting provisions set out as a note under section 331 of this title] may be cited as the 'Stop Counterfeit Drugs by Regulating and Enhancing Enforcement Now Act' or the 'SCREEN Act'.''

Pub. L. 115–271, title III, § 3021, Oct. 24, 2018, 132 Stat. 3938, provided that: ''This chapter [chapter 3 (§§ 3021, 3022) of subtitle A of title III of Pub. L. 115–271, enacting section 384g of this title and amending sections 331, 335a, and 381 of this title] may be cited as the 'Stop Illicit Drug Importation Act of 2018'.''

Pub. L. 115–271, title III, § 3031, Oct. 24, 2018, 132 Stat. 3940, provided that: ''This chapter [chapter 4 (§§ 3031, 3032) of subtitle A of title III of Pub. L. 115–271, amending section 355–1 of this title] may be cited as the 'Securing Opioids and Unused Narcotics with Deliberate Disposal and Packaging Act of 2018' or the 'SOUND Disposal and Packaging Act'.''

Pub. L. 115–234, § 1, Aug. 14, 2018, 132 Stat. 2427, provided that: ''This Act [amending sections 348, 352, 360b, 360ccc, 360ccc–1, 379j–11 to 379j–13, 379–21, 379j–22, and 2102 of this title, enacting provisions set out as notes under this section and sections 348, 352, 360b, 360ccc–1, 379j–11 to 379j–13, 379j–21, and 379j–22 of this title, and repealing provisions set out as notes under sections 379j–12, 379j–13, 379j–21, and 379j–22 of this title] may be cited as the 'Animal Drug and Animal Generic Drug User Fee Amendments of 2018'.''

Pub. L. 115–234, title I, § 101(a), Aug. 14, 2018, 132 Stat. 2428, provided that: ''This title [amending sections 379j–11 to 379j–13 of this title, enacting provisions set out as notes under sections 379j–11 to 379j–13 of this title, and repealing provisions set out as notes under sections 379j–12 and 379j–13 of this title] may be cited as the 'Animal Drug User Fee Amendments of 2018'.''

Pub. L. 115–234, title II, § 201(a), Aug. 14, 2018, 132 Stat. 2432, provided that: ''This title [amending sections 379j–21 and 379j–22 of this title, enacting provisions set out as notes under sections 379j–21 and 379j–22 of this title, and repealing provisions set out as notes under sections 379j–21 and 379j–22 of this title] may be cited as the 'Animal Generic Drug User Fee Amendments of 2018'.''

Pub. L. 115–176, § 1, May 30, 2018, 132 Stat. 1372, provided that: ''This Act [enacting section 360bbb–0a of this title and provisions set out as a note under section 360bbb–0a of this title] may be cited as the 'Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017'.''

Short Title of 2017 Amendment

Pub. L. 115–52, § 1, Aug. 18, 2017, 131 Stat. 1005, provided that: ''This Act [see Tables for classification] may be cited as the 'FDA Reauthorization Act of 2017'.''

Pub. L. 115–52, title I, § 101(a), Aug. 18, 2017, 131 Stat. 1006, provided that: ''This title [amending sections 379h, 379h–2, and 379j–12 of this title, enacting provisions set out as notes under sections 379g and 379h–2 of this title, and repealing provisions set out as notes under sections 379g and 379h–2 of this title] may be cited as the 'Prescription Drug User Fee Amendments of 2017'.''

Pub. L. 115–52, title II, § 201(a), Aug. 18, 2017, 131 Stat. 1013, provided that: ''This title [amending sections 360d, 360e, 360m, 379d–3, 379i, 379j, 379j–1, and 379k–1 of this title, enacting provisions set out as notes under sections 379i and 379j–1 of this title, and repealing provisions set out as a note under section 379i of this title] may be cited as the 'Medical Device User Fee Amendments of 2017'.''

Pub. L. 115–52, title III, § 301(a), Aug. 18, 2017, 131 Stat. 1020, provided that: ''This title [amending sections 379j–41 to 379j–43 of this title, enacting provisions set out as notes under sections 379j–41 and 379j–43 of this title, and repealing provisions set out as notes under

sections 379j–41 and 379j–43 of this title] may be cited as the 'Generic Drug User Fee Amendments of 2017'.''

Pub. L. 115–52, title IV, §401(a), Aug. 18, 2017, 131 Stat. 1028, provided that: ''This title [amending sections 379j–51 to 379j–53 of this title, enacting provisions set out as notes under sections 379j–51 and 379j–53 of this title, and repealing provisions set out as notes under sections 379j–51 and 379j–53 of this title] may be cited as the 'Biosimilar User Fee Amendments of 2017'.''

SHORT TITLE OF 2016 AMENDMENT

Pub. L. 114–229, §1, Sept. 30, 2016, 130 Stat. 943, provided that: ''This Act [amending section 360ff of this title and enacting provisions set out as a note under section 360ff of this title] may be cited as the 'Advancing Hope Act of 2016'.''

Pub. L. 114–146, §1, Apr. 19, 2016, 130 Stat. 357, provided that: ''This Act [amending section 360n of this title] may be cited as the 'Adding Zika Virus to the FDA Priority Review Voucher Program Act'.''

SHORT TITLE OF 2015 AMENDMENT

Pub. L. 114–114, §1, Dec. 28, 2015, 129 Stat. 3129, provided that: ''This Act [amending section 331 of this title and enacting provisions set out as notes under section 331 of this title] may be cited as the 'Microbead-Free Waters Act of 2015'.''

Pub. L. 114–89, §1, Nov. 25, 2015, 129 Stat. 698, provided that: ''This Act [amending sections 355, 360b, 360ccc to 360ccc–2, 811, 823, and 953 of this title, section 156 of Title 35, Patents, and section 262 of Title 42, The Public Health and Welfare] may be cited as the 'Improving Regulatory Transparency for New Medical Therapies Act'.''

SHORT TITLE OF 2014 AMENDMENT

Pub. L. 113–233, §1, Dec. 16, 2014, 128 Stat. 2127, provided that: ''This Act [amending section 360n of this title] may be cited as the 'Adding Ebola to the FDA Priority Review Voucher Program Act'.''

Pub. L. 113–195, §1, Nov. 26, 2014, 128 Stat. 2035, provided that: ''This Act [enacting part I of subchapter V of this chapter and provisions set out as a note under section 360fff of this title] may be cited as the 'Sunscreen Innovation Act'.''

SHORT TITLE OF 2013 AMENDMENT

Pub. L. 113–54, §1, Nov. 27, 2013, 127 Stat. 587, provided that: ''This Act [enacting part H of subchapter V and subpart 9 of part C of subchapter VII of this chapter and sections 353a–1 and 353b of this title, amending sections 331, 333, 352 to 353a, 353b, 353c, and 360eee–1 of this title, and enacting provisions set out as notes under this section and sections 331, 333, and 353 of this title] may be cited as the 'Drug Quality and Security Act'.''

Pub. L. 113–54, title I, §101, Nov. 27, 2013, 127 Stat. 587, provided that: ''This Act [probably means ''This title'', enacting subpart 9 of part C of subchapter VII of this chapter and sections 353a–1 and 353b of this title, amending sections 331, 352, 353a, 353b, and 353c of this title, and enacting provisions set out as notes under this section and section 331 of this title] may be cited as the 'Compounding Quality Act'.''

Pub. L. 113–54, title II, §201, Nov. 27, 2013, 127 Stat. 599, provided that: ''This title [enacting part H of subchapter V of this chapter, amending sections 331, 333, 352, 353, and 360eee–1 of this title, and enacting provisions set out as notes under sections 331, 333, and 353 of this title] may be cited as the 'Drug Supply Chain Security Act'.''

Pub. L. 113–14, §1, June 13, 2013, 127 Stat. 451, provided that: ''This Act [amending sections 379j–11 to 379j–13, 379j–21, and 379j–22 of this title, enacting provisions set out as notes under this section and sections 379j–11 to 379j–13, 379j–21, and 379j–22 of this title, and repealing provisions set out as notes under sections 379j–11, 379j–21, and 379j–22 of this title] may be cited as the 'Animal Drug and Animal Generic Drug User Fee Reauthorization Act of 2013'.''

Pub. L. 113–14, title I, §101(a), June 13, 2013, 127 Stat. 451, provided that: ''This title [amending sections 379j–11 to 379j–13 of this title, enacting provisions set out as notes under sections 379j–11 to 379j–13 of this title, and repealing provisions set out as notes under section 379j–11 of this title] may be cited as the 'Animal Drug User Fee Amendments of 2013'.''

Pub. L. 113–14, title II, §201(a), June 13, 2013, 127 Stat. 464, provided that: ''This title [amending sections 379j–21 and 379j–22 of this title, enacting provisions set out as notes under sections 379j–21 and 379j–22 of this title, and repealing provisions set out as notes under sections 379j–21 and 379j–22 of this title] may be cited as the 'Animal Generic Drug User Fee Amendments of 2013'.''

SHORT TITLE OF 2012 AMENDMENT

Pub. L. 112–193, §1, Oct. 5, 2012, 126 Stat. 1443, provided that: ''This Act [amending sections 352, 379j, and 379j–42 of this title and enacting provisions set out as a note under section 379j–42 of this title] may be cited as the 'FDA User Fee Corrections Act of 2012'.''

Pub. L. 112–144, §1, July 9, 2012, 126 Stat. 993, provided that: ''This Act [see Tables for classification] may be cited as the 'Food and Drug Administration Safety and Innovation Act'.''

Pub. L. 112–144, title I, §101(a), July 9, 2012, 126 Stat. 996, provided that: ''This title [amending sections 379g, 379h, and 379h–2 of this title, enacting provisions set out as notes under sections 379g and 379h–2 of this title, and repealing provisions set out as notes under sections 379g and 379h–2 of this title] may be cited as the 'Prescription Drug User Fee Amendments of 2012'.''

Pub. L. 112–144, title II, §201(a), July 9, 2012, 126 Stat. 1002, provided that: ''This title [enacting section 379d–3 of this title, amending sections 360e, 379i, 379j, and 379j–1 of this title, enacting provisions set out as notes under section 379i of this title, and repealing provisions set out as notes under section 379i of this title] may be cited as the 'Medical Device User Fee Amendments of 2012'.''

Pub. L. 112–144, title III, §301(a), July 9, 2012, 126 Stat. 1008, provided that: ''This title [enacting sections 379d–4 and 379j–41 to 379j–43 of this title, amending sections 352 and 379d–3 of this title, and enacting provisions set out as notes under sections 379j–41 and 379j–43 of this title] may be cited as the 'Generic Drug User Fee Amendments of 2012'.''

Pub. L. 112–144, title IV, §401(a), July 9, 2012, 126 Stat. 1026, provided that: ''This title [enacting sections 379j–51 to 379j–53 of this title, amending sections 379d–4 and 379g of this title, and enacting provisions set out as notes under sections 379g, 379j–51, and 379j–53 of this title] may be cited as the 'Biosimilar User Fee Act of 2012'.''

SHORT TITLE OF 2009 AMENDMENT

Pub. L. 111–31, div. A, §1(a), June 22, 2009, 123 Stat. 1776, provided that: ''This division [enacting subchapter IX of this chapter, amending sections 321, 331, 333, 334, 355, 360m, 372 to 374, 375, 379a, 381, 391 to 393, 394 to 399a, and 679 of this title and sections 1333, 1334, 4402, 4406, and 4408 of Title 15, Commerce and Trade, enacting provisions set out as notes under sections 331, 333, 387, and 387c of this title and sections 1333 and 4402 of Title 15, and amending provisions set out as notes under this section and section 392 of this title] may be cited as the 'Family Smoking Prevention and Tobacco Control Act'.''

SHORT TITLE OF 2008 AMENDMENT

Pub. L. 110–316, title I, §101(a), Aug. 14, 2008, 122 Stat. 3509, provided that: ''This title [enacting section 379j–13 of this title, amending sections 360b, 379j–11, and 379j–12 of this title, and enacting provisions set out as notes under sections 360b and 379j–11 of this title] may be cited as the 'Animal Drug User Fee Amendments of 2008'.''

Pub. L. 110–316, title II, §201(a), Aug. 14, 2008, 122 Stat. 3515, provided that: ''This title [enacting sections

379j–21 and 379j–22 of this title, amending sections 379k, 379*l*, and 379*o* of this title, and enacting provisions set out as notes under sections 379j–21 and 379j–22 of this title] may be cited as the 'Animal Generic Drug User Fee Act of 2008'.''

SHORT TITLE OF 2007 AMENDMENT

Pub. L. 110–85, § 1, Sept. 27, 2007, 121 Stat. 823, provided that: ''This Act [enacting part I of subchapter VII of this chapter, chapter 26 of this title, sections 350f, 353b, 355–1, 355d, 355e, 360a, 360e–1, 360n, 360bbb–5, 360bbb–6, 379d–1, 379d–2, 379h–1, 379h–2, 379j–1, and 399a of this title, and section 247d–5a of Title 42, The Public Health and Welfare, amending sections 321, 331, 333, 334, 352, 355, 355a, 355c, 360, 360e, 360i, 360j, 360*l*, 360m, 360ee, 374, 379g, 379h, 379i, 379j, 379j–11, 379*l*, 381, and 393a of this title and sections 247d–3b, 262, 282, 283, 283a–2, 283a–3, 284m, 285g–10, 288–6, and 290b of Title 42, enacting provisions set out as notes under this section and sections 331, 350f, 352, 355, 355a, 355c, 360j, 379g, 379h, 379h–2, 379i, and 2110 of this title and section 282 of Title 42, and amending provisions set out as notes under section 284m of Title 42] may be cited as the 'Food and Drug Administration Amendments Act of 2007'.''

Pub. L. 110–85, title I, § 101(a), Sept. 27, 2007, 121 Stat. 825, provided that: ''This title [enacting sections 379h–1 and 379h–2 of this title, amending sections 379g, 379h, and 379j–11 of this title, and enacting provisions set out as notes under sections 379g, 379h, and 379h–2 of this title] may be cited as the 'Prescription Drug User Fee Amendments of 2007'.''

Pub. L. 110–85, title II, § 201(a), Sept. 27, 2007, 121 Stat. 842, provided that: ''This title [enacting section 379j–1 of this title, amending sections 333, 360, 360i, 360m, 374, 379i, and 379j of this title, and enacting provisions set out as notes under section 379i of this title] may be cited as the 'Medical Device User Fee Amendments of 2007'.''

Pub. L. 110–85, title III, § 301, Sept. 27, 2007, 121 Stat. 859, provided that: ''This title [enacting section 360e–1 of this title, amending sections 360j, 360*l*, and 393a of this title and section 282 of Title 42, The Public Health and Welfare, enacting provisions set out as notes under section 360j of this title and section 282 of Title 42, and amending provisions set out as a note under section 284m of Title 42] may be cited as the 'Pediatric Medical Device Safety and Improvement Act of 2007'.''

Pub. L. 110–85, title IV, § 401, Sept. 27, 2007, 121 Stat. 866, provided that: ''This title [enacting section 355d of this title, amending section 355c of this title, and enacting provisions set out as a note under section 355c of this title] may be cited as the 'Pediatric Research Equity Act of 2007'.''

Pub. L. 110–85, title V, § 501, Sept. 27, 2007, 121 Stat. 876, provided that: ''This title [amending section 355a of this title and sections 284m, 285g–10, 288–6, and 290b of Title 42, The Public Health and Welfare, enacting provisions set out as a note under section 355a of this title, and amending provisions set out as a note under section 284m of Title 42] may be cited as the 'Best Pharmaceuticals for Children Act of 2007'.''

SHORT TITLE OF 2006 AMENDMENT

Pub. L. 109–462, § 1, Dec. 22, 2006, 120 Stat. 3469, provided that: ''This Act [enacting sections 379aa and 379aa–1 of this title, amending sections 331, 343, 352, and 381 of this title, and enacting provisions set out as notes under sections 331, 343, 352, 379aa, and 381 of this title] may be cited as the 'Dietary Supplement and Nonprescription Drug Consumer Protection Act'.''

SHORT TITLE OF 2005 AMENDMENTS

Pub. L. 109–59, title VII, § 7201, Aug. 10, 2005, 119 Stat. 1911, provided that: ''This subtitle [subtitle B (§§ 7201–7204) of title VII of Pub. L. 109–59, enacting section 350e of this title, amending sections 331, 342, and 373 of this title and section 5701 of Title 49, Transportation, omitting sections 5702 to 5714 of Title 49, and enacting provisions set out as a note under section 331 of this title] may be cited as the 'Sanitary Food Transportation Act of 2005'.''

Pub. L. 109–43, § 1, Aug. 1, 2005, 119 Stat. 439, provided that: ''This Act [amending sections 352 and 379j of this title, enacting provisions set out as a note under section 352 of this title, and amending provisions set out as notes under sections 352 and 379i of this title] may be cited as the 'Medical Device User Fee Stabilization Act of 2005'.''

SHORT TITLE OF 2004 AMENDMENTS

Pub. L. 108–282, title I, § 101, Aug. 2, 2004, 118 Stat. 891, provided that: ''This title [enacting sections 360ccc to 360ccc–2 of this title, amending sections 321, 331, 352, 353, 354, and 360b of this title, enacting provisions set out as notes under sections 360ccc and 393 of this title, and amending provisions set out as a note under section 360b of this title] may be cited as the 'Minor Use and Minor Species Animal Health Act of 2004'.''

Pub. L. 108–282, title II, § 201, Aug. 2, 2004, 118 Stat. 905, provided that: ''This title [enacting section 374a of this title and section 242r of Title 42, The Public Health and Welfare, amending sections 321, 343, and 343–1 of this title, and enacting provisions set out as notes under sections 321 and 343 of this title and sections 243 and 300d–2 of Title 42] may be cited as the 'Food Allergen Labeling and Consumer Protection Act of 2004'.''

Pub. L. 108–214, § 1, Apr. 1, 2004, 118 Stat. 572, provided that: ''This Act [amending sections 331, 352, 360, 360e, 374, 379i, and 379j of this title and provisions set out as notes under sections 352, 360*l*, and 379j of this title] may be cited as the 'Medical Devices Technical Corrections Act'.''

SHORT TITLE OF 2003 AMENDMENTS

Pub. L. 108–155, § 1, Dec. 3, 2003, 117 Stat. 1936, provided that: ''This Act [enacting section 355c of this title, amending sections 355, 355a, and 355b of this title and sections 262 and 284m of Title 42, The Public Health and Welfare, enacting provisions set out as a note under section 355c of this title, and amending provisions set out as notes under section 355a of this title and section 284m of Title 42] may be cited as the 'Pediatric Research Equity Act of 2003'.''

Pub. L. 108–130, § 1, Nov. 18, 2003, 117 Stat. 1361, provided that: ''This Act [enacting sections 379j–11 and 379j–12 of this title and provisions set out as notes under section 379j–11 of this title] may be cited as the 'Animal Drug User Fee Act of 2003'.''

SHORT TITLE OF 2002 AMENDMENTS

Pub. L. 107–281, § 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, § 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, 360*l*, 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, § 501, June 12, 2002, 116 Stat. 687, provided that: ''This subtitle [subtitle A (§§ 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, § 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, 284*l*, 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, §1(a) [title VII, §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, §1(a) [title VII, §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, §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, §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, 379*l*, 379*o*, 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, 360*l*, 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, 360*l*, 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, §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, §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, §1, 110 Stat. 1489, which is set out as a note under section 136 of Title 7, Agriculture.]

Pub. L. 104–134, title II, §2101(a), Apr. 26, 1996, 110 Stat. 1321–313, provided that: ''This chapter [chapter 1A (§§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, §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, §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, §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, §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, §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, §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, §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, 360*l*, 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, §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, §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, §1(a), Nov. 28, 1990, 104 Stat. 4511, provided that: ''This Act [enacting sections 360*l* 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, §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, §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, §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, §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, §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, §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, §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, §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, §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, §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, 254*o*, 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, §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, §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, §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 289*l*–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, §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, §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, §1, Oct. 18, 1968, 82 Stat. 1173, provided that: ''This Act [enacting provisions now comprising part C (§§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, §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, §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, §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, §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, §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'.''

SEVERABILITY

Pub. L. 113–54, title I, §106(b), Nov. 27, 2013, 127 Stat. 598, provided that: ''If any provision of this Act [see Short Title of 2013 Amendment note above] (including the amendments made by this Act) is declared unconstitutional, or the applicability of this Act (including the amendments made by this Act) to any person or circumstance is held invalid, the constitutionality of the remainder of this Act (including the amendments made by this Act) and the applicability thereof to other persons and circumstances shall not be affected.''

Pub. L. 110–85, title XI, §1105, Sept. 27, 2007, 121 Stat. 975, provided that: ''If any provision of this Act [see Short Title of 2007 Amendment note above], an amendment made [by] this Act, or the application of such provision or amendment to any person or circumstance is held to be unconstitutional, the remainder of this Act, the amendments made by this Act, and the application of the provisions of such to any person or circumstances shall not be affected thereby.''

HAZARDOUS SUBSTANCES

Federal Hazardous Substances Act as not modifying this chapter, see Pub. L. 86–613, §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.

SUBCHAPTER II—DEFINITIONS

§ 321. Definitions; generally

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,[1] 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)(1) 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—

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

(B) 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

(C) 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. The term ''device'' does not include software functions excluded pursuant to section 360j(*o*) of this title.

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

(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

[1] So in original. Probably should be ''Pharmacopeia,''.