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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 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,