Sec. 387c. Misbranded tobacco products.
387d. Submission of health information to the Secretary.
387f. General provisions respecting control of tobacco products.
387g. Enforcement action plan for advertising and promotion restrictions.
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SUBCHAPTER X—MISCELLANEOUS
391. Separability clause.
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393. Food and Drug Administration.
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396. Practice of medicine.
397. Contracts for expert review.
398. Notices to States regarding imported food.
399. Grants to enhance food safety.
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SUBCHAPTER I—SHORT TITLE
§ 301. Short title
This chapter may be cited as the Federal Food, Drug, and Cosmetic Act.

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 sections 403(e)(1) [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]; 504(e) [354(e) of this title]; and 506(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) [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]; and 506(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 chapter, 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 372 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 [section 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 [section 352(b), (d) to (h) of this title], insofar as such provisions relate to drugs to which section 505 [section 355 of this title] of such Act applies.

**Effective Date**


**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, 375a, 381, 391 to 393, 394 to 396d, 397, and 439 of this title and sections 1333, 1334, 4462, 4466, and 4408 of Title 15, Commerce and Trade, enacting provisions set out as notes under sections 331, 333, 337, and 367 of this title and sections 1333 and 4462 of Title 15, and amending provisions set out as notes under sections 379–10 and section 392 of this title] may be cited as the ‘Family Smoking Prevention and Tobacco Control Act’.”

**Short Title of 2008 Amendment**


**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 IX of this chapter, chapter 26 of this title, sections 350f, 353b, 355–1, 355d, 355e, 360a, 360e–1, 360m, 360bb–5, 360bb–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, 355, 355a, 355c, 360, 360e, 360i, 360j, 360m, 360ee, 374, 379g, 379h, 379i, 379j, 379l, 379r, 381, and 393a of this title and sections 247d–3b, 262, 282, 283a–2, 284a, 284m, 285c–10, 288–6, and 2906 of Title 42, enacting provisions set out as notes under this section and sections 311, 350f, 352, 355, 355a, 355c, 360, 360i, 360j, 360m, 360m, 374, 379g, 379h, 379i, 379j, 379l, 379r, 381, and 393a of this title and sections 247d–3b, 262, 282, 283a–2, 284a–3, 284m, 285c–10, 288–6, and 2906 of Title 42, enacting provisions set out as notes under sections 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 379–1 and 379h–2 of this title, amending sections 379g, 379i, and 379–11 of this title, and enacting provisions set out as notes under sections 379 and 379j 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 379–1 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 379 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 360, 360i, and 385a of this title and section 282 of Title 42, The Public Health and Welfare, enacting provisions set out as notes under section 360 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 379j, 379j–1, and 379j–2 of this title and section 289g–3 of Title 42, The Public Health and Welfare, amending sections 321, 331, 333, 355a, 355b, 356, 360c, 360e, 360m, and 374 of this title, and enacting provisions set out as notes under sections 331, 343, 352, 390b, 390i, 390j, and 397 of this title and section 289g–3 of Title 42] may be cited as the ‘Medical Device User Fee and Modernization Act of 2006’.”

**SHORT TITLE OF 2005 AMENDMENTS**


**SHORT TITLE OF 2004 AMENDMENTS**


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

**SHORT TITLE OF 2003 AMENDMENTS**

Pub. L. 108–115, §1(a), Nov. 21, 1999, 113 Stat. 1513, provided that: “This Act [amending sections 355c of this title, amending sections 355, 355a, and 355b of this title and sections 262 and 264m 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 264m of Title 42] may be cited as the ‘Pediatric Research Equity 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 360ccc 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 Disease Orphan Product Development Act of 2002’.”


Pub. L. 107–108, §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, 335, 355a, and 379h of this title and sections 262, 264k, 264i, 263a–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 289f 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, §748(a)], Oct. 28, 2000, 114 Stat. 1549, 1548A–40, provided that: “This Act [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**


**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, 360bb to 360bb–2, 379f, 379i, 379l, 379o, and 379p of this title and provisions set out as notes under sections 356 and 357 of this title] may be cited as the ‘Food and Drug Administration Modernization Act of 1997’.”

**SHORT TITLE OF 1996 AMENDMENTS**


**Short Title of 1994 Amendments**


**Short Title of 1993 Amendment**

Pub. L. 103–80, §1, Aug. 13, 1993, 107 Stat. 773, provided that: “This Act [enacting sections 379g and 379h of this title, transferring sections 372a, 376, and 378e of this title, and amending 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 1993’.”

**Short Title of 1992 Amendments**


**Short Title of 1992 Amendment**

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 378e of this title to sections 376, 379e and 379h, respectively, of this title] may be cited as the ‘Dietary Supplement Health and Education Act of 1994’.”

**Short Title of 1990 Amendment**

Pub. L. 101–635, §1(a), Nov. 28, 1990, 104 Stat. 4583, provided that: “That this Act [enacting section 360aa of this title, and amending provisions set out as notes under sections 333, 360c, 360i, 360j, 360hh and 360j of this title] may be cited as the ‘Drug Price Competition and Patent Term Restoration Act’.”

**Short Title of 1988 Amendments**

Pub. L. 100–670, title V, §501, Nov. 4, 1988, 102 Stat. 3120, provided that: “This title [enacting section 393 of this title, amending sections 353 and 3516 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’.”

**Short Title of 1987 Amendment**

Pub. L. 100–293, §1(a), Apr. 22, 1988, 102 Stat. 95, provided that: “This Act [amending sections 331, 333, 335, 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 User Fee Act of 1989’.”

**Short Title of 1986 Amendment**


**Short Title of 1985 Amendment**


**Short Title of 1984 Amendment**


**Short Title of 1983 Amendments**

under section 348 of this title] may be cited as the ‘Saccharin Study and Labeling Act Amendment of 1983’.


SHORT TITLE OF 1962 AMENDMENT


SHORT TITLE OF 1958 AMENDMENT

Pub. L. 85–929, §1, Sept. 6, 1958, 72 Stat. 1784, 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 ’Food Additives Amendment of 1958’.’’

SHORT TITLE OF 1958 AMENDMENT

Pub. L. 85–929, §1, Sept. 6, 1958, 72 Stat. 1784, 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 ’Food Additives Amendment of 1958’.’’

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’.’’


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 362 of this title] may be cited as the ’Drug Abuse Control Amendments of 1965’.’’