

sified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

CONSTRUCTION

Nothing in this section to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

SEARCH ENGINE

Pub. L. 111-353, title II, §206(b), Jan. 4, 2011, 124 Stat. 3942, provided that: “Not later than 90 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall modify the Internet Web site of the Food and Drug Administration to include a search engine that—

“(1) is consumer-friendly, as determined by the Secretary; and

“(2) provides a means by which an individual may locate relevant information regarding each article of food subject to a recall under section 423 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350l] and the status of such recall (such as whether a recall is ongoing or has been completed).”

§ 350l-1. Annual report to Congress

(1) In general

Not later than 2 years after January 4, 2011, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 350l of this title (as added by subsection (a))¹ and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

(2) Content

The report under paragraph (1) shall include, with respect to the report year—

(A) the identity of each article of food that was the subject of a public health advisory described in paragraph (1), an opportunity to cease distribution and recall under subsection (a) of section 350l of this title, or a mandatory recall order under subsection (b) of such section;

(B) the number of responsible parties, as defined in section 350f of this title, formally given the opportunity to cease distribution of an article of food and recall such article, as described in section 350l(a) of such title;

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under section 350l(a) of this title;

(D) the number of recall orders issued under section 350l(b) of this title; and

(E) a description of any instances in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under section 350l(b) of this title or

a public health advisory described in paragraph (1).

(Pub. L. 111-353, title II, §206(f), Jan. 4, 2011, 124 Stat. 3943.)

REFERENCES IN TEXT

Subsection (a), referred to in par. (1), means subsection (a) of section 206 of Pub. L. 111-353.

CODIFICATION

Section was enacted as part of the FDA Food Safety Modernization Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

CONSTRUCTION

Nothing in this section to be construed to alter jurisdiction and authorities established under certain other Acts or in a manner inconsistent with international agreements to which the United States is a party, see sections 2251 and 2252 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this

¹ See References in Text note below.

title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

(b) Strength, quality, or purity differing from official compendium

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) Mixture with or substitution of another substance

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

(e) Devices not in conformity with performance standards

(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 360d of this title unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 360d(c) of this title unless such device is in all respects in conformity with such standard.

(f) Certain class III devices

(1) If it is a class III device—

(A)(i) which is required by an order issued under subsection (b) of section 360e of this title to have an approval under such section of an application for premarket approval and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii)(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the issuance of such order, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)(i) which was classified under section 360c(f) of this title into class III, which under section 360e(a) of this title is required to have in effect an approved application for premarket approval, and which is not exempt from section 360e of this title under section 360j(g) of this title, and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(l) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

(2)(A) In the case of a device classified under section 360c(f) of this title into class III and intended solely for investigational use, paragraph¹ (1)(B) shall not apply with respect to such device during the period ending on the ninetieth day after the date of the promulgation of the regulations prescribing the procedures and conditions required by section 360j(g)(2) of this title.

(B) In the case of a device subject to an order issued under subsection (b) of section 360e of this title, paragraph¹ (1) shall not apply with respect to such device during the period ending—

(i) on the last day of the thirtieth calendar month beginning after the month in which the classification of the device in class III became effective under section 360c of this title, or

(ii) on the ninetieth day after the date of the issuance of such order,

whichever occurs later.

(3) In the case of a device with respect to which a regulation was promulgated under section 360e(b) of this title prior to July 9, 2012, a reference in this subsection to an order issued under section 360e(b) of this title shall be deemed to include such regulation.

(g) Banned devices

If it is a banned device.

(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions

If it is a device and the methods used in, or the facilities or controls used for, its manufacture,

¹ So in original. Probably should be "subparagraph".

packing, storage, or installation are not in conformity with applicable requirements under section 360j(f)(1) of this title or an applicable condition prescribed by an order under section 360j(f)(2) of this title.

(i) Failure to comply with requirements under which device was exempted for investigational use

If it is a device for which an exemption has been granted under section 360j(g) of this title for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(j) Delayed, denied, or limited inspection; refusal to permit entry or inspection

If it is a drug or device and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

For purposes of paragraph (a)(2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

(June 25, 1938, ch. 675, § 501, 52 Stat. 1049; Pub. L. 86-618, title I, § 102(b)(1), July 12, 1960, 74 Stat. 398; Pub. L. 87-781, title I, § 101, Oct. 10, 1962, 76 Stat. 780; Pub. L. 90-399, § 101(a), July 13, 1968, 82 Stat. 343; Pub. L. 94-295, §§ 3(d), 9(b)(1), May 28, 1976, 90 Stat. 576, 583; Pub. L. 101-629, § 9(b), Nov. 28, 1990, 104 Stat. 4521; Pub. L. 102-571, title I, § 107(8), Oct. 29, 1992, 106 Stat. 4499; Pub. L. 105-115, title I, § 121(b)(1), title II, § 204(c), Nov. 21, 1997, 111 Stat. 2320, 2336; Pub. L. 112-144, title VI, § 608(b)(2), title VII, §§ 707(a), 711, July 9, 2012, 126 Stat. 1058, 1068, 1071; Pub. L. 115-52, title VII, § 702(c), Aug. 18, 2017, 131 Stat. 1056.)

AMENDMENTS

2017—Par. (j). Pub. L. 115-52 inserted "or device" after "drug".

2012—Pub. L. 112-144, § 711, inserted concluding provisions.

Par. (f)(1)(A)(i). Pub. L. 112-144, § 608(b)(2)(A)(i), substituted "an order issued" for "a regulation promulgated".

Par. (f)(1)(A)(ii)(I). Pub. L. 112-144, § 608(b)(2)(A)(ii), substituted "issuance of such order" for "promulgation of such regulation".

Par. (f)(2)(B). Pub. L. 112-144, § 608(b)(2)(B), substituted "an order issued" for "a regulation promulgated" in introductory provisions and "issuance of such order" for "promulgation of such regulation" in subcl. (ii).

Par. (f)(3). Pub. L. 112-144, § 608(b)(2)(C), added subpar. (3).

Par. (j). Pub. L. 112-144, § 707(a), added par. (j).

1997—Par. (a)(2)(C). Pub. L. 105-115, § 121(b)(1), inserted "; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron

emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess;" before "or (3)".

Par. (e). Pub. L. 105-115, § 204(c), designated existing provisions as subpar. (1) and added subpar. (2).

1992—Par. (a)(4). Pub. L. 102-571 substituted "379e(a)" for "376(a)" in cls. (A) and (B).

1990—Par. (f)(1). Pub. L. 101-629, § 9(b), which directed the amendment of subpars. (A) to (C) of par. (f), was executed by making the amendments in cls. (A) to (C) of subpar. (1) of par. (f) as follows to reflect the probable intent of Congress: in cl. (A)(ii)(II), substituted ", suspended, or withdrawn" for "or withdrawn"; in cl. (B)(ii), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect"; and in cl. (C), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect".

1976—Par. (a). Pub. L. 94-295, § 9(b)(1), substituted "(3) if its" for "(3) if it is a drug and its" in cl. (3), substituted "(4) if (A) it bears or contains" for "(4) if (A) it is a drug which bears or contains" in cl. (4)(A), and substituted "drugs or devices" for "drugs" in cl. (4)(B).

Pars. (e) to (i). Pub. L. 94-295, § 3(d), added pars. (e) to (i).

1968—Par. (a). Pub. L. 90-399 added cls. (5) and (6).

1962—Par. (a). Pub. L. 87-781 designated existing provisions of cl. (2) as (A) and added (B).

1960—Par. (a). Pub. L. 86-618 substituted provisions in cl. (4) relating to unsafe color additives for provisions which related to a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 354 of this title.

EFFECTIVE AND TERMINATION DATES OF 1997 AMENDMENT

Pub. L. 105-115, title I, § 121(b)(2), Nov. 21, 1997, 111 Stat. 2320, provided that: "Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act [Nov. 21, 1997] or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B) [section 121(c)(1)(B) of Pub. L. 105-115, set out as a note under section 355 of this title], whichever is later."

Amendment by Pub. L. 105-115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

EFFECTIVE DATE OF 1968 AMENDMENT

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.

EFFECTIVE DATE OF 1962 AMENDMENT; EXCEPTIONS

Amendment by 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.

EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the 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; POSTPONEMENT

Par. (a)(4) effective Jan. 1, 1940, see act June 23, 1939, ch. 242, 53 Stat. 853, set out as an Effective Date; Postponement in Certain Cases note under section 301 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 notes set out under section 321 of this title.

APPROVAL BY REGULATION PRIOR TO JULY 9, 2012

Pub. L. 112-144, title VI, §608(b)(3), July 9, 2012, 126 Stat. 1059, provided that: “The amendments made by this subsection [amending this section and section 360e of this title] shall have no effect on a regulation that was promulgated prior to the date of enactment of this Act [July 9, 2012] requiring that a device have an approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) of an application for pre-market approval.”

GUIDANCE

Pub. L. 112-144, title VII, §707(b), July 9, 2012, 126 Stat. 1068, provided that: “Not later than 1 year after the date of enactment of this section [July 9, 2012], the Secretary of Health and Human Services shall issue guidance that defines the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351(j)] (as added by subsection (a)).”

§ 352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

(1) If its labeling is false or misleading in any particular. Health care economic information provided to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis, carrying out its responsibilities for the selection of drugs for coverage or reimbursement, shall not be considered to be false or misleading under this paragraph if the health care economic information relates to an indication approved under section 355 of this title or under section 262(a) of title 42 for such drug, is based on competent and reliable scientific evidence, and includes, where applicable, a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug under section 355 of this title or under section 262 of title 42. The requirements set forth in section 355(a) of this title or in subsections (a) and (k) of section 262 of title 42 shall not apply to health care economic information provided to such a payor, committee, or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request.

(2)(A) For purposes of this paragraph,¹ the term “health care economic information” means any analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences,

¹ So in original. The term “health care economic information” appears only in par. (1).

which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug. Such analysis may be comparative to the use of another drug, to another health care intervention, or to no intervention.

(B) Such term does not include any analysis that relates only to an indication that is not approved under section 355 of this title or under section 262 of title 42 for such drug.

(b) Package form; contents of label

If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) Repealed. Pub. L. 105-115, title I, § 126(b), Nov. 21, 1997, 111 Stat. 2327**(e) Designation of drugs or devices by established names**

(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Sec-