

tended for human use,” for “prescription drugs” in two places.

Pub. L. 105–115, §125(b)(2)(L), struck out “, section 357(d) or (g),” before “section 3601”.

Subsec. (f). Pub. L. 105–115, §210(b), added subsec. (f). 1993—Subsec. (a)(1). Pub. L. 103–80 substituted a comma for semicolon after “finished and unfinished materials” and “section 355(i) or (k)” for “section 355(i) or (j)”.

1980—Subsec. (a)(1). Pub. L. 96–359, §4(1), (2), restructured first five sentences of former subsec. (a) as par. (1) and, as so restructured, inserted reference to paragraph (3) and substituted “(A)” and “(B)” for “(1)” and “(2)”, respectively.

Subsec. (a)(2). Pub. L. 96–359, §4(3), redesignated sixth sentence of former subsec. (a) as par. (2) and, as so redesignated, substituted reference to second sentence of paragraph (1) for reference to former second sentence of this subsection, and “(A)”, “(B)”, “(C)”, and “(D)”, for “(1)”, “(2)”, “(3)”, and “(4)”, respectively.

Subsec. (a)(3). Pub. L. 96–359, §4(4), added par. (3). 1976—Subsec. (a). Pub. L. 94–295, §6(a)–(c), expanded existing provisions to encompass medical devices by inserting references to factories, warehouses, establishments, and consulting laboratories in which restricted devices are manufactured, processed, packed, or held, inspections relating to devices, reporting and inspection regulations issued pursuant to sections 3601 and 360j(g) of this title, and the manufacture and processing of devices.

Subsec. (e). Pub. L. 94–295, §6(d), added subsec. (e). 1962—Subsec. (a). Pub. L. 87–781, §201(a), extended the inspection, where prescription drugs are manufactured, processed, packed, or held, to all things bearing on whether adulterated or misbranded drugs, or any which may not be manufactured, introduced in interstate commerce, or sold or offered for sale under any provision of this chapter, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this chapter, but excluded from such inspection, data concerning finance, sales other than shipment, pricing, personnel other than qualifications of technical and professional personnel, research other than relating to new drugs subject to reporting, provided that provisions of second sentence of this subsection shall be inapplicable to pharmacies, practitioners and other persons enumerated in pars. (1) to (4), and struck out “are held” before “after such introduction”.

Subsec. (b). Pub. L. 87–781, §201(b), inserted “consulting laboratory” after “warehouse”.

1953—Act Aug. 7, 1953, designated existing provisions as subsec. (a) and amended them by substituting provisions permitting entry and inspection upon presentation of appropriate credentials and a written notice to the owner, operator, or agent in charge for provisions which authorized entry and inspection only after making a request and obtaining permission from the owner, operator, or custodian, and inserting provisions requiring a separate written notice for each inspection but not for each entry made during the period covered by the inspection, and directing that the inspection shall be conducted within reasonable limits, in a reasonable manner and completed with reasonable promptness, and added subsecs. (b) to (d).

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by sections 210(b) and 412(b) of 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 a note under section 321 of this title.

EFFECTIVE DATE OF 1962 AMENDMENT

Amendment by Pub. L. 87–781 effective Oct. 10, 1962, see section 203 of Pub. L. 87–781, set out as a note under section 332 of this title.

CONSTRUCTION OF 2011 AMENDMENT

Nothing in amendment by Pub. L. 111–353 to be construed to apply to certain alcohol-related facilities, 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 2206, 2251, and 2252 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.

AUTHORITY OF SECRETARY PRIOR TO OCTOBER 10, 1962

Section 201(d) of Pub. L. 87–781 provided that: “Nothing in the amendments made by subsections (a) and (b) of this section [amending this section] shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act [Oct. 10, 1962].”

§ 374a. Inspections relating to food allergens

The Secretary of Health and Human Services shall conduct inspections consistent with the authority under section 374 of this title of facilities in which foods are manufactured, processed, packed, or held—

(1) to ensure that the entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food with residues of major food allergens that are not intentional ingredients of the food; and

(2) to ensure that major food allergens are properly labeled on foods.

(Pub. L. 108–282, title II, §205, Aug. 2, 2004, 118 Stat. 909.)

CODIFICATION

Section was enacted as a part of the Food Allergen Labeling and Consumer Protection Act of 2004, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§ 375. Publicity

(a) Reports

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

(June 25, 1938, ch. 675, §705, 52 Stat. 1057; Pub. L. 111–31, div. A, title I, §103(j), June 22, 2009, 123 Stat. 1837.)

AMENDMENTS

2009—Subsec. (b). Pub. L. 111–31 inserted “tobacco products,” after “devices,”.

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.

§ 376. Examination of sea food on request of packer; marking food with results; fees; penalties

The Secretary, upon application of any packer of any sea food for shipment or sale within the jurisdiction of this chapter, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this chapter and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service. Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is authorized to promulgate regulations governing the sanitary and other conditions under which the service herein provided shall be granted and maintained, and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates, or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year or a fine of not less than \$1,000 nor more than \$5,000, or both such imprisonment and fine.

(June 25, 1938, ch. 675, § 706, formerly § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204; amended Aug. 27, 1935, ch. 739, 49 Stat. 871; 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; renumbered § 702A of act June 25, 1938, July 12, 1943, ch. 221, title II, 57 Stat. 500; Pub. L. 102-300, § 6(b)(2), June 16, 1992, 106 Stat. 240; renumbered § 706, Pub. L. 102-571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498; Pub. L. 103-80, § 3(dd)(2), Aug. 13, 1993, 107 Stat. 779.)

CODIFICATION

Section was formerly classified to section 372a of this title prior to renumbering by Pub. L. 102-571.

Section, which formerly was not a part of the Federal Food, Drug, and Cosmetic Act, originally was classified to section 14a of this title. Section 1002(a) of act June 25, 1938, set out as an Effective Date note under section 301 of this title, provided that the section should remain in force and effect and be applicable to the provisions of this chapter. Act July 12, 1943, renumbered this section as 702A of the Federal Food, Drug, and Cosmetic Act.

PRIOR PROVISIONS

A prior section 376, act June 25, 1938, ch. 675, § 706, 52 Stat. 1058, as amended, which related to listing and certification of color additives for foods, drugs, devices, and cosmetics, was renumbered section 721 of act June 25, 1938, by Pub. L. 102-571, title I, § 106(4), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 379e of this title.

AMENDMENTS

1993—Pub. L. 103-80 struck out “of Agriculture” after “Secretary” in two places.

1992—Pub. L. 102-300, which directed the amendment of the section by striking out “of Health, Education, and Welfare” wherever appearing, could not be executed because such words did not appear in the original statutory text. See 1993 Amendment note above and Transfer of Functions note below.

TRANSFER OF FUNCTIONS

Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by Pub. L. 96-88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, which is classified to section 3508(b) of Title 20, Education.

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.

§ 377. Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests

The Secretary, in carrying into effect the provisions of this chapter, is authorized on and after July 12, 1943, to cooperate with associations and scientific societies in the revision of the United States Pharmacopoeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration.

(July 12, 1943, ch. 221, title II, 57 Stat. 500; 1953 Reorg. Plan No. 1, § 5, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631.)

CODIFICATION

Section was enacted as part of the Labor-Federal Security Appropriation Act, 1944, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

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.

§ 378. Advertising of foods

(a) Determination of misbranding; notification of Federal Trade Commission by Secretary; contents

(1) Except as provided in subsection (c) of this section, before the Secretary may initiate any action under subchapter III of this chapter—

(A) with respect to any food which the Secretary determines is misbranded under section 343(a)(2) of this title because of its advertising,

or

(B) with respect to a food's advertising which the Secretary determines causes the food to be so misbranded,