

[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,

the Secretary shall, in accordance with paragraph (2), notify in writing the Federal Trade Commission of the action the Secretary proposes to take respecting such food or advertising.

(2) The notice required by paragraph (1) shall—

(A) contain (i) a description of the action the Secretary proposes to take and of the advertising which the Secretary has determined causes a food to be misbranded, (ii) a statement of the reasons for the Secretary's determination that such advertising has caused such food to be misbranded, and

(B) be accompanied by the records, documents, and other written materials which the Secretary determines supports his determination that such food is misbranded because of such advertising.

(b) Action by Federal Trade Commission precluding action by Secretary; exception

(1) If the Secretary notifies the Federal Trade Commission under subsection (a) of this section

of action proposed to be taken under subchapter III of this chapter with respect to a food or food advertising and the Commission notifies the Secretary in writing, within the 30-day period beginning on the date of the receipt of such notice, that—

(A) it has initiated under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] an investigation of such advertising to determine if it is prohibited by such Act or any order or rule under such Act,

(B) it has commenced (or intends to commence) a civil action under section 5, 13, or 19 [15 U.S.C. 45, 53, or 57b] with respect to such advertising or the Attorney General has commenced (or intends to commence) a civil action under section 5 [15 U.S.C. 45] with respect to such advertising,

(C) it has issued and served (or intends to issue and serve) a complaint under section 5(b) of such Act [15 U.S.C. 45(b)] respecting such advertising, or

(D) pursuant to section 16(b) of such Act [15 U.S.C. 56(b)] it has made a certification to the Attorney General respecting such advertising,

the Secretary may not, except as provided by paragraph (2), initiate the action described in the Secretary's notice to the Federal Trade Commission.

(2) If, before the expiration of the 60-day period beginning on the date the Secretary receives a notice described in paragraph (1) from the Federal Trade Commission in response to a notice of the Secretary under subsection (a) of this section—

(A) the Commission or the Attorney General does not commence a civil action described in subparagraph (B) of paragraph (1) of this subsection respecting the advertising described in the Secretary's notice,

(B) the Commission does not issue and serve a complaint described in subparagraph (C) of such paragraph respecting such advertising, or

(C) the Commission does not (as described in subparagraph (D) of such paragraph) make a certification to the Attorney General respecting such advertising, or, if the Commission does make such a certification to the Attorney General respecting such advertising, the Attorney General, before the expiration of such period, does not cause appropriate criminal proceedings to be brought against such advertising,

the Secretary may, after the expiration of such period, initiate the action described in the notice to the Commission pursuant to subsection (a) of this section. The Commission shall promptly notify the Secretary of the commencement by the Commission of such a civil action, the issuance and service by it of such a complaint, or the causing by the Attorney General of criminal proceedings to be brought against such advertising.

(c) Secretary's determination of imminent hazard to health as suspending applicability of provisions

The requirements of subsections (a) and (b) of this section do not apply with respect to action under subchapter III of this chapter with respect

to any food or food advertising if the Secretary determines that such action is required to eliminate an imminent hazard to health.

(d) Coordination of action by Secretary with Federal Trade Commission

For the purpose of avoiding unnecessary duplication, the Secretary shall coordinate any action taken under subchapter III of this chapter because of advertising which the Secretary determines causes a food to be misbranded with any action of the Federal Trade Commission under the Federal Trade Commission Act [15 U.S.C. 41 et seq.] with respect to such advertising.

(June 25, 1938, ch. 675, §707, as added Pub. L. 94-278, title V, §502(b), Apr. 22, 1976, 90 Stat. 412.)

REFERENCES IN TEXT

The Federal Trade Commission Act, referred to in subsecs. (b) and (d), is act Sept. 26, 1914, ch. 311, 38 Stat. 717, as amended, which is classified generally to subchapter I (§41 et seq.) of chapter 2 of Title 15, Commerce and Trade. For complete classification of this Act to the Code, see section 58 of Title 15 and Tables.

§ 379. Confidential information

The Secretary may provide any information which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section to a person other than an officer or employee of the Department if the Secretary determines such other person requires the information in connection with an activity which is undertaken under contract with the Secretary, which relates to the administration of this chapter, and with respect to which the Secretary (or an officer or employee of the Department) is not prohibited from using such information. The Secretary shall require as a condition to the provision of information under this section that the person receiving it take such security precautions respecting the information as the Secretary may by regulation prescribe.

(June 25, 1938, ch. 675, §708, as added Pub. L. 94-295, §8, May 28, 1976, 90 Stat. 582.)

§ 379a. Presumption of existence of jurisdiction

In any action to enforce the requirements of this chapter respecting a device, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

(June 25, 1938, ch. 675, §709, as added Pub. L. 94-295, §8, May 28, 1976, 90 Stat. 583; amended Pub. L. 105-115, title IV, §419, Nov. 21, 1997, 111 Stat. 2379.)

AMENDMENTS

1997—Pub. L. 105-115 substituted “a device, food, drug, or cosmetic” for “a device”.

EFFECTIVE DATE OF 1997 AMENDMENT

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 a note under section 321 of this title.

§ 379b. Consolidated administrative and laboratory facility

(a) Authority

The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

(b) Awarding of contract

The Secretary shall solicit contract proposals under subsection (a) of this section from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) Donations

In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section \$100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

(June 25, 1938, ch. 675, §710, as added Pub. L. 101-635, title I, §101, Nov. 28, 1990, 104 Stat. 4583.)

§ 379c. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, §711, as added Nov. 28, 1990, Pub. L. 101-635, title II, §201, 104 Stat. 4584, which related to recovery and retention of fees for freedom of information requests, was renumbered section 731 of act June 25, 1938, by Pub. L. 102-571, title I, §106(6), Oct. 29, 1992, 106 Stat. 4499, and transferred to section 379f of this title.

§ 379d. Automation of Food and Drug Administration

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

(b) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, §711, formerly §712, as added Pub. L. 101-635, title IV, §401, Nov. 28, 1990,