704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(4)], as amended by paragraph (1);

''(ii) processes for responding to such requests electronically or in physical form; and

''(iii) factors the Secretary intends to consider in evaluating whether such records and other information are provided within a reasonable timeframe, within reasonable limits, and in a reasonable manner, accounting for resource and other limitations that may exist, including for small businesses.

''(B) TIMING.—The Secretary shall—

''(i) not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], issue draft guidance under subparagraph (A); and

''(ii) not later than 1 year after the close of the comment period for such draft guidance, issue final guidance under subparagraph (A).''

Pub. L. 115–52, title VII, §702(b), Aug. 18, 2017, 131 Stat. 1055, provided that:

''(1) DRAFT GUIDANCE.—Not later than 18 months after the date of enactment of this Act [Aug. 18, 2017], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance that—

''(A) specifies how the Food and Drug Administration will implement the processes and standards described in paragraph (1) of subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a), and the requirements described in paragraph (2) of such subsection (h);

''(B) provides for standardized methods for communications described in such paragraphs;

''(C) establishes, with respect to inspections of both domestic and foreign device establishments (as referred to in section 510(h)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360(h)(2)], as amended by subsection (a) [of section 701 of Pub. L. 115–52]), a standard timeframe for such inspections—

''(i) that occurs over consecutive days; and

''(ii) to which each investigator conducting such an inspection shall adhere unless the investigator identifies to the establishment involved a reason that more time is needed to conduct such investigation; and

''(D) identifies practices for investigators and device establishments to facilitate the continuity of inspections of such establishments.

''(2) FINAL GUIDANCE.—Not later than 1 year after providing notice and opportunity for public comment on the draft guidance issued under paragraph (1), the Secretary of Health and Human Services shall issue final guidance to implement subsection (h) of section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374), as added by subsection (a).''

INSPECTIONS

Pub. L. 115–52, title VIII, §806, Aug. 18, 2017, 131 Stat. 1073, provided that:

''Within 6 months of the date of enactment of this Act [Aug. 18, 2017], the Secretary of Health and Human Services shall develop and implement a protocol for expediting review of timely responses to reports of observations from an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374). Such protocol shall—

''(1) apply to responses to such reports pertaining to applications submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)—

''(A) for which the approval is dependent upon remediation of conditions identified in the report;

''(B) for which concerns related to observations from an inspection under such section 704 are the only barrier to approval; and

''(C) where the drug that is the subject of the application is a drug—

''(i) for which there are not more than 3 other approved applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) that reference the same listed drug and for which there are less than 6 abbreviated new drug applications tentatively approved; or

''(ii) that is included on the list under section 506E of such Act (21 U.S.C. 356e);

''(2) address expedited re-inspection of facilities, as appropriate; and

''(3) establish a 6-month timeline for completion of review of such responses to such reports.''

AUTHORITY OF SECRETARY PRIOR TO OCTOBER 10, 1962

Pub. L. 87–781, title II, §201(d), Oct. 10, 1962, 76 Stat. 793, 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].''

**Executive Documents**

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.

## § 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.)

**Editorial Notes**

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.)

**Editorial Notes**

AMENDMENTS

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

**Executive Documents**

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.)

**Editorial Notes**

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.

**Statutory Notes and Related Subsidiaries**

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.

**Executive Documents**

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.

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

The Secretary, in carrying into effect the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], 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.)

**Editorial Notes**

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in text, is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For com-