''(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''(2) FINAL GUIDANCE.—Not later than 1 year after providing notice and opportunity for public comment on the draft guidance issued under paragraph (1), the Secretary of Health and Human Services shall issue final guidance to implement subsection (h) of section 704 of the Federal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