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.

GUIDANCE

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''(1) DRAFT GUIDANCE.—Not later than 18 months after the date of enactment of this Act [Aug. 18, 2017], the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue draft guidance that—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

§ 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.