

sion of this chapter or under the Public Health Service Act [42 U.S.C. 201 et seq.].

**(j) Coordinated communication**

**(1) In general**

To assist in carrying out the requirements of this subsection, the Secretary shall establish an incident command operation or a similar operation within the Department of Health and Human Services that will operate not later than 24 hours after the initiation of a mandatory recall or the recall of an article of food for which the use of, or exposure to, such article will cause serious adverse health consequences or death to humans or animals.

**(2) Requirements**

To reduce the potential for miscommunication during recalls or regarding investigations of a food borne illness outbreak associated with a food that is subject to a recall, each incident command operation or similar operation under paragraph (1) shall use regular staff and resources of the Department of Health and Human Services to—

(A) ensure timely and coordinated communication within the Department, including enhanced communication and coordination between different agencies and organizations within the Department;

(B) ensure timely and coordinated communication from the Department, including public statements, throughout the duration of the investigation and related foodborne illness outbreak;

(C) identify a single point of contact within the Department for public inquiries regarding any actions by the Secretary related to a recall;

(D) coordinate with Federal, State, local, and tribal authorities, as appropriate, that have responsibilities related to the recall of a food or a foodborne illness outbreak associated with a food that is subject to the recall, including notification of the Secretary of Agriculture and the Secretary of Education in the event such recalled food is a commodity intended for use in a child nutrition program (as identified in section 1769f(b) of title 42); and

(E) conclude operations at such time as the Secretary determines appropriate.

**(3) Multiple recalls**

The Secretary may establish multiple or concurrent incident command operations or similar operations in the event of multiple recalls or foodborne illness outbreaks necessitating such action by the Department of Health and Human Services.

(June 25, 1938, ch. 675, §423, as added Pub. L. 111-353, title II, §206(a), Jan. 4, 2011, 124 Stat. 3939.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (i), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

CONSTRUCTION

Nothing in this section to be construed 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 2251 and 2252 of this title.

SEARCH ENGINE

Pub. L. 111-353, title II, §206(b), Jan. 4, 2011, 124 Stat. 3942, provided that: “Not later than 90 days after the date of enactment of this Act [Jan. 4, 2011], the Secretary shall modify the Internet Web site of the Food and Drug Administration to include a search engine that—

“(1) is consumer-friendly, as determined by the Secretary; and

“(2) provides a means by which an individual may locate relevant information regarding each article of food subject to a recall under section 423 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 350f] and the status of such recall (such as whether a recall is ongoing or has been completed).”

**§ 3501-1. Annual report to Congress**

**(1) In general**

Not later than 2 years after January 4, 2011, and annually thereafter, the Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the use of recall authority under section 350f of this title (as added by subsection (a))<sup>1</sup> and any public health advisories issued by the Secretary that advise against the consumption of an article of food on the ground that the article of food is adulterated and poses an imminent danger to health.

**(2) Content**

The report under paragraph (1) shall include, with respect to the report year—

(A) the identity of each article of food that was the subject of a public health advisory described in paragraph (1), an opportunity to cease distribution and recall under subsection (a) of section 350f of this title, or a mandatory recall order under subsection (b) of such section;

(B) the number of responsible parties, as defined in section 350f of this title, formally given the opportunity to cease distribution of an article of food and recall such article, as described in section 350f(a) of such title;

(C) the number of responsible parties described in subparagraph (B) who did not cease distribution of or recall an article of food after given the opportunity to cease distribution or recall under section 350f(a) of this title;

(D) the number of recall orders issued under section 350f(b) of this title; and

(E) a description of any instances in which there was no testing that confirmed adulteration of an article of food that was the subject of a recall under section 350f(b) of this title or a public health advisory described in paragraph (1).

(Pub. L. 111-353, title II, §206(f), Jan. 4, 2011, 124 Stat. 3943.)

<sup>1</sup> See References in Text note below.

## REFERENCES IN TEXT

Subsection (a), referred to in par. (1), means subsec. (a) of section 206 of Pub. L. 111-353.

## CODIFICATION

Section was enacted as part of the FDA Food Safety Modernization Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

## CONSTRUCTION

Nothing in this section to be construed 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 2251 and 2252 of this title.

## SUBCHAPTER V—DRUGS AND DEVICES

## PART A—DRUGS AND DEVICES

**§ 351. Adulterated drugs and devices**

A drug or device shall be deemed to be adulterated—

**(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture**

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if (A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 379e(a) of this title, or (B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 379e(a) of this title; or (5) if it is a new animal drug which is unsafe within the meaning of section 360b of this title; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 360b of this title.

**(b) Strength, quality, or purity differing from official compendium**

If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

**(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium**

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

**(d) Mixture with or substitution of another substance**

If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

**(e) Devices not in conformity with performance standards**

(1) If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 360d of this title unless such device is in all respects in conformity with such standard.

(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 360d(c) of this title unless such device is in all respects in conformity with such standard.

**(f) Certain class III devices**

(1) If it is a class III device—

(A)(i) which is required by an order issued under subsection (b) of section 360e of this