[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.

NOTIFICATION OF FDA INTENT TO REGULATE LABORATORY-DEVELOPED TESTS

Pub. L. 112–144, title XI, § 1143, July 9, 2012, 126 Stat. 1130, provided that the Food and Drug Administration could not issue any draft or final guidance on the regulation of laboratory-developed tests under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) without, at least 60 days prior to such issuance, notifying the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the Administration's intent to take such action and including in such notification the anticipated details of such action, and that such provision ceased to have force or effect on the date that was 5 years after the date of enactment of Pub. L. 112–144, which was approved July 9, 2012.

APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS

Pub. L. 105–115, title IV, § 403, Nov. 21, 1997, 111 Stat. 2367, provided that:

''(a) STANDARDS.—Not later than 180 days after the date of enactment of this Act [Nov. 21, 1997], the Secretary of Health and Human Services shall publish in the Federal Register standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

''(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act [Nov. 21, 1997], the Secretary shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

''(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

''(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

''(3) define supplemental applications that are eligible for priority review.

''(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

''(1) encouraging the prompt review of supplemental applications for approved articles; and

''(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

''(d) COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.''

HEARINGS PENDING ON APRIL 15, 1954, WITH RESPECT TO FOOD STANDARDS

Provisions of this chapter in effect prior to Apr. 15, 1954, as applicable with respect to hearings begun prior to such date under subsection (e) of this section, regarding food standards, see Savings Provisions note set out under section 341 of this title.

§ 372. Examinations and investigations

(a) Authority to conduct

(1)(A) The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(B)(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this chapter.

(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this chapter on Indian country without the express written consent of the Indian tribe involved.

(2)(A) In addition to the authority established in paragraph (1), the Secretary, pursuant to a memorandum of understanding between the Secretary and the head of another Federal department or agency, is authorized to conduct examinations and investigations for the purposes of this chapter through the officers and employees of such other department or agency, subject to subparagraph (B). Such a memorandum shall include provisions to ensure adequate training of such officers and employees to conduct the examinations and investigations. The memorandum of understanding shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations or investigations performed under this section by the officers or employees of the other department or agency.

(B) A memorandum of understanding under subparagraph (A) between the Secretary and another Federal department or agency is effective only in the case of examinations or inspections at facilities or other locations that are jointly regulated by the Secretary and such department or agency.

(C) For any fiscal year in which the Secretary and the head of another Federal department or agency carries out one or more examinations or inspections under a memorandum of understanding under subparagraph (A), the Secretary and the head of such department or agency shall with respect to their respective departments or agencies submit to the committees of jurisdiction (authorizing and appropriating) in the House of Representatives and the Senate a report that provides, for such year—

(i) the number of officers or employees that carried out one or more programs, projects, or activities under such memorandum;

(ii) the number of additional articles that were inspected or examined as a result of such memorandum; and

(iii) the number of additional examinations or investigations that were carried out pursuant to such memorandum.

(3) In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Sec-

retary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this chapter, the facilities at his disposal will permit of such inspection.

(4) For the purposes of this subsection, the term ''United States'' means the States and the District of Columbia.

(b) Availability to owner of part of analysis samples

Where a sample of a food, drug, or cosmetic is collected for analysis under this chapter the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this chapter.

(c) Records of other departments and agencies

For purposes of enforcement of this chapter, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department duly authorized by the Secretary to make such inspection.

(d) Information on patents for drugs

The Secretary is authorized and directed, upon request from the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

(e) Powers of enforcement personnel

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 334 of this title;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

(June 25, 1938, ch. 675, §702, 52 Stat. 1056; Pub. L. 87–781, title III, §§307(b), 308, Oct. 10, 1962, 76 Stat. 796; Pub. L. 89–74, §8(a), July 15, 1965, 79 Stat. 234; Pub. L. 91–513, title II, §701(f), Oct. 27, 1970, 84 Stat. 1282; Pub. L. 102–300, §6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103–80, §3(dd)(2), Aug. 13, 1993, 107 Stat. 779; Pub. L. 106–113, div. B, §1000(a)(9) [title IV, §4732(b)(12)], Nov. 29, 1999, 113 Stat. 1536, 1501A–584; Pub. L. 107–188, title III, §314, June 12, 2002, 116 Stat. 674; Pub. L. 111–31, div. A, title I, §103(g), June 22, 2009, 123 Stat. 1837.)

AMENDMENTS

2009—Subsec. (a)(1). Pub. L. 111–31 designated existing provisions as subpar. (A) and added subpar. (B).

2002—Subsec. (a). Pub. L. 107–188 inserted ''(1)'' before ''The Secretary is authorized to conduct'', added par. (2), inserted ''(3)'' before ''In the case of food packed'', and substituted ''(4) For the purposes of this subsection,'' for ''For the purposes of this subsection''.

1999—Subsec. (d). Pub. L. 106–113, in first sentence, substituted ''Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office'' for ''Commissioner of Patents'' and ''Director'' for ''Commissioner''.

1993—Subsec. (c). Pub. L. 103–80 struck out ''of Agriculture'' after ''Department''.

1992—Subsec. (c). Pub. L. 102–300, which directed the amendment of subsec. (c) by striking out ''of Health, Education, and Welfare'', 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.

1970—Subsec. (e). Pub. L. 91–513 struck out reference to depressant or stimulant drugs.

1965—Subsec. (e). Pub. L. 89–74 added subsec. (e).

1962—Subsec. (a). Pub. L. 87–781, §307(b), inserted ''the Commonwealth of Puerto Rico or'' before ''a Territory the Secretary''.

Subsec. (d). Pub. L. 87–781, §308, added subsec. (d).

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by Pub. L. 106–113 effective 4 months after Nov. 29, 1999, see section 1000(a)(9) [title IV, §4731] of Pub. L. 106–113, set out as a note under section 1 of Title 35, Patents.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–513 effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91–513, set out as an Effective Date note under section 801 of this title.

EFFECTIVE DATE OF 1965 AMENDMENT

Amendment by Pub. L. 89–74 effective July 15, 1965, see section 11 of Pub. L. 89–74, set out as a note under section 321 of this title.

SAVINGS PROVISION

Amendment by Pub. L. 91–513 not to affect or abate any prosecutions for any violation of law or any civil seizures or forfeitures and injunctive proceedings commenced prior to the effective date of such amendment, and all administrative proceedings pending before the Bureau of Narcotics and Dangerous Drugs [now Drug Enforcement Administration] on Oct. 27, 1970, to be continued and brought to final determination in accord with laws and regulations in effect prior to Oct. 27, 1970, see section 702 of Pub. L. 91–513, set out as a note under section 321 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 note set out under section 41 of this title.

§ 372a. Transferred

CODIFICATION

Section, act June 25, 1938, ch. 675, § 702A, formerly June 30, 1906, ch. 3915, § 10A, as added June 22, 1934, ch. 712, 48 Stat. 1204, and amended, which related to examination of sea food, was renumbered section 706 of act June 25, 1938, by Pub. L. 102–571, title I, § 106(3), Oct. 29, 1992, 106 Stat. 4498, and transferred to section 376 of this title.

§ 373. Records

(a) In general

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, tobacco products, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, tobacco product, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, tobacco product, or cosmetic to which such request relates, except that evidence obtained under this section, or any evidence which is directly or indirectly derived from such evidence, shall not be used in a criminal prosecution of the person from whom obtained, and except that carriers shall not be subject to the other provisions of this chapter by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, tobacco products, or cosmetics in the usual course of business as carriers, except as provided in subsection (b).

(b) Food transportation records

A shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 350e of this title shall, on request of an officer or employee designated by the Secretary, permit the officer or employee, at reasonable times, to have access to and to copy all records that the Secretary requires to be kept under section 350e(c)(1)(E) of this title.

(June 25, 1938, ch. 675, § 703, 52 Stat. 1057; Pub. L. 91–452, title II, § 230, Oct. 15, 1970, 84 Stat. 930; Pub. L. 103–80, § 3(z), Aug. 13, 1993, 107 Stat. 778; Pub. L. 109–59, title VII, § 7202(c), Aug. 10, 2005, 119 Stat. 1913; Pub. L. 111–31, div. A, title I, § 103(h), June 22, 2009, 123 Stat. 1837.)

AMENDMENTS

2009—Subsec. (a). Pub. L. 111–31 inserted ''tobacco product,'' after ''device,'' in two places and ''tobacco products,'' after ''devices,'' in two places.

2005—Pub. L. 109–59 struck out ''of interstate shipment'' after ''Records'' in section catchline, designated existing provisions as subsec. (a), inserted subsec. heading, substituted ''carriers, except as provided in subsection (b)'' for ''carriers'' before period at end, and added subsec. (b).

1993—Pub. L. 103–80 substituted '', except that'' for '': *Provided*, That'' and '', and except that'' for '': *Provided further*, That''.

1970—Pub. L. 91–452 inserted '', or any evidence which is directly or indirectly derived from such evidence,'' after ''under this section''.

EFFECTIVE DATE OF 2005 AMENDMENT

Amendment by Pub. L. 109–59 effective Oct. 1, 2005, see section 7204 of Pub. L. 109–59, set out as a note under section 331 of this title.

EFFECTIVE DATE OF 1970 AMENDMENT

Amendment by Pub. L. 91–452 effective on sixtieth day following Oct. 15, 1970, and not to affect any immunity to which any individual is entitled under this section by reason of any testimony given before sixtieth day following Oct. 15, 1970, see section 260 of Pub. L. 91–452, set out as an Effective Date; Savings Provision note under section 6001 of Title 18, Crimes and Criminal Procedure.

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.

§ 374. Inspection

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 350c of this title, when the standard for records inspection under paragraph (1) or (2) of section 350c(a) of this title applies, subject to the limitations established in section 350c(d) of this title. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs,