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.)

Editorial Notes

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''.

Statutory Notes and Related Subsidiaries

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.

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.

§ 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 a facility (as defined in section 364 of this title) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 364a, 364b, and 364f of this title, when the standard for records inspection under such section applies. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, 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, nonprescription drugs intended for human use, devices, or tobacco products which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) of this title, section 360i of this title, section 360j(g) of this title, or subchapter IX and data relating to other drugs, devices, or tobacco products which in the case of a new drug would be subject to reporting or in-

spection under lawful regulations issued pursuant to section 355(j) of this title). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;

(C) persons who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices, solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 350a of this title applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records—

(A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 350a of this title, or

(B) required to be maintained under section 350a of this title.

(4)(A) Any records or other information that the Secretary may inspect under this section from a person that owns or operates an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or a site or facility that is subject to inspection under paragraph (5)(C), shall, upon the request of the Secretary, be provided to the Secretary by such person, in advance of or in lieu of an inspection, within a reasonable timeframe, within reasonable limits, and in a reasonable manner, and in either electronic or physical form, at the expense of such person. The Secretary's request shall include a sufficient description of the records or other information requested and a rationale for requesting such records or other information in advance of, or in lieu of, an inspection.

(B) Upon receipt of the records requested under subparagraph (A), the Secretary shall provide to the person confirmation of receipt.

(C) The Secretary may rely on any records or other information that the Secretary may inspect under this section to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, or to resolve deficiencies identified during such inspections, if applicable and appropriate.

(D) Nothing in this paragraph supplants the authority of the Secretary to conduct inspections otherwise permitted under this chapter in order to ensure compliance with this chapter.

(5)(A) The Secretary may, to ensure the accuracy and reliability of studies and records or other information described in subparagraph (B) and to assess compliance with applicable requirements under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], enter sites and facilities specified in subparagraph (C) in order to inspect such records or other information.

(B) An inspection under this paragraph shall extend to all records and other information related to the studies and submissions described in subparagraph (E), including records and information related to the conduct, results, and analyses of, and the protection of human and animal trial participants participating in, such studies.

(C)(i) The sites and facilities subject to inspection by the Secretary under this paragraph are those owned or operated by a person described in clause (ii) and which are (or were) utilized by such person in connection with—

(I) developing an application or other submission to the Secretary under this chapter or the Public Health Service Act related to marketing authorization for a product described in paragraph (1);

(II) preparing, conducting, or analyzing the results of a study described in subparagraph (E); or

(III) holding any records or other information described in subparagraph (B).

(ii) A person described in this clause is—

(I) the sponsor of an application or submission specified in subparagraph (E);

(II) a person engaged in any activity described in clause (i) on behalf of such a sponsor, through a contract, grant, or other business arrangement with such sponsor;

(III) an institutional review board, or other individual or entity, engaged by contract, grant, or other business arrangement with a nonsponsor in preparing, collecting, or analyzing records or other information described in subparagraph (B); or

(IV) any person not otherwise described in this clause that conducts, or has conducted, a study described in subparagraph (E) yielding records or other information described in subparagraph (B).

(D)(i) Subject to clause (ii), an entity that owns or operates any site or facility subject to inspection under this paragraph shall provide the Secretary with access to records and other information described in subparagraph (B) that

is held by or under the control of such entity, including—

(I) permitting the Secretary to record or copy such information for purposes of this paragraph;

(II) providing the Secretary with access to any electronic information system utilized by such entity to hold, process, analyze, or transfer any records or other information described in subparagraph (B); and

(III) permitting the Secretary to inspect the facilities, equipment, written procedures, processes, and conditions through which records or other information described in subparagraph (B) is or was generated, held, processed, analyzed, or transferred.

(ii) Nothing in clause (i) shall negate, supersede, or otherwise affect the applicability of provisions, under this or any other Act, preventing or limiting the disclosure of confidential commercial information or other information considered proprietary or trade secret.

(iii) An inspection under this paragraph shall be conducted at reasonable times and within reasonable limits and in a reasonable manner.

(E) The studies and submissions described in this subparagraph are each of the following:

(i) Clinical and nonclinical studies submitted to the Secretary in support of, or otherwise related to, applications and other submissions to the Secretary under this chapter or the Public Health Service Act for marketing authorization of a product described in paragraph (1).

(ii) Postmarket safety activities conducted under this chapter or the Public Health Service Act.

(iii) Any other clinical investigation of—

(I) a drug subject to section 355 or 360b of this title or section 262 of title 42; or

(II) a device subject to section 360j(g) of this title.

(iv) Any other submissions made under this chapter or the Public Health Service Act with respect to which the Secretary determines an inspection under this paragraph is warranted in the interest of public health.

(F) This paragraph clarifies the authority of the Secretary to conduct inspections of the type described in this paragraph and shall not be construed as a basis for inferring that, prior to December 29, 2022, the Secretary lacked the authority to conduct such inspections, including under this chapter or the Public Health Service Act.

(b) Written report to owner; copy to Secretary

(1) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (A) consists in whole or in part of any filthy, putrid, or decomposed substance, or (B) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

(2) In carrying out this subsection with respect to any establishment manufacturing a drug approved under subsection (c) or (j) of section 355 of this title for which a notification has been submitted in accordance with section 356c of this title is, or has been in the last 5 years, listed on the drug shortage list under section 356e of this title, or that is described in section 355(j)(11)(A) of this title, a copy of the report shall be sent promptly to the appropriate offices of the Food and Drug Administration with expertise regarding drug shortages.

(c) Receipt for samples taken

If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) Analysis of samples furnished owner

Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(e) Accessibility of records

Every person required under section 360i or 360j(g) of this title to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to, and to copy and verify, such records.

(f) Recordkeeping

(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

(2) Within 15 days after the receipt of a written request from the Secretary to an accredited person described in paragraph (3) for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.

(3) For purposes of paragraphs (1) and (2), an accredited person described in this paragraph is a person who—

(A) is accredited under subsection (g); or

(B) is accredited under section 360m of this title.

(g) Inspections by accredited persons

(1) The Secretary shall, subject to the provisions of this subsection, accredit persons for the purpose of conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 360(h) of this title or are inspections of such establishments required to register under section 360(i) of this title. The owner or operator of such an establishment that is eligible under paragraph (6) may, from the list published under paragraph (4), select an accredited person to conduct such inspections.

(2) The Secretary shall publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1). Thereafter, the Secretary shall inform those requesting accreditation, within 60 days after the receipt of such request, whether the request for accreditation is adequate for review, and the Secretary shall promptly act on the request for accreditation. Any resulting accreditation shall state that such person is accredited to conduct inspections at device establishments identified in paragraph (1). The accreditation of such person shall specify the particular activities under this subsection for which such person is accredited.

(3) An accredited person shall, at a minimum, meet the following requirements:

(A) Such person may not be an employee of the Federal Government.

(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of articles regulated under this chapter and which has no organizational, material, or financial affiliation (including a consultative affiliation) with such a manufacturer, supplier, or vendor.

(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

(D) Such person shall not engage in the design, manufacture, promotion, or sale of articles regulated under this chapter.

(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices, and such person shall agree in writing that at a minimum the person will—

(i) certify that reported information accurately reflects data reviewed, inspection observations made, other matters that relate to or may influence compliance with this chapter, and recommendations made during an inspection or at an inspection's closing meeting;

(ii) limit work to that for which competence and capacity are available;

(iii) treat information received, records, reports, and recommendations as confidential commercial or financial information or trade secret information, except such information may be made available to the Secretary;

(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(v) protect against the use, in carrying out paragraph (1), of any officer or employee of the accredited person who has a financial conflict of interest regarding any product regulated under this chapter, and annually make available to the public disclosures of the extent to which the accredited person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

(F) Such person shall notify the Secretary of any withdrawal, suspension, restriction, or expiration of certificate of conformance with the quality systems standard referred to in paragraph (7) for any device establishment that such person inspects under this subsection not later than 30 days after such withdrawal, suspension, restriction, or expiration.

(G) Such person may conduct audits to establish conformance with the quality systems standard referred to in paragraph (7).

(4) The Secretary shall publish on the Internet site of the Food and Drug Administration a list of persons who are accredited under paragraph (2). Such list shall be updated to ensure that the identity of each accredited person, and the particular activities for which the person is accredited, is known to the public. The updating of such list shall be no later than one month after the accreditation of a person under this subsection or the suspension or withdrawal of accreditation, or the modification of the particular activities for which the person is accredited.

(5)(A) To ensure that persons accredited under this subsection continue to meet the standards of accreditation, the Secretary shall (i) audit the performance of such persons on a periodic basis through the review of inspection reports and inspections by persons designated by the Secretary to evaluate the compliance status of a device establishment and the performance of accredited persons, and (ii) take such additional measures as the Secretary determines to be appropriate.

(B) The Secretary may withdraw accreditation of any person accredited under paragraph (2), after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the standards of accreditation, poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection. The Secretary may suspend the accreditation of such person during the pendency of the process under the preceding sentence.

(6)(A) Subject to subparagraphs (B) and (C), a device establishment is eligible for inspection by persons accredited under paragraph (2) if the following conditions are met:

(i) The Secretary classified the results of the most recent inspection of the establishment as ''no action indicated'' or ''voluntary action indicated''.

(ii) With respect to inspections of the establishment to be conducted by an accredited person, the owner or operator of the establishment submits to the Secretary a notice that—

(I) provides the date of the last inspection of the establishment by the Secretary and the classification of that inspection;

(II) states the intention of the owner or operator to use an accredited person to conduct inspections of the establishment;

(III) identifies the particular accredited person the owner or operator intends to select to conduct such inspections; and

(IV) includes a certification that, with respect to the devices that are manufactured, prepared, propagated, compounded, or processed in the establishment—

(aa) at least 1 of such devices is marketed in the United States; and

(bb) at least 1 of such devices is marketed, or is intended to be marketed, in 1 or more foreign countries, 1 of which countries certifies, accredits, or otherwise recognizes the person accredited under paragraph (2) and identified under subclause (III) as a person authorized to conduct inspections of device establishments.

(B)(i) Except with respect to the requirement of subparagraph (A)(i), a device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 30 days after receiving such notice, issues a response that—

(I) denies clearance to participate as provided under subparagraph (C); or

(II) makes a request under clause (ii).

(ii) The Secretary may request from the owner or operator of a device establishment in response to the notice under subparagraph (A)(ii) with respect to the establishment, or from the particular accredited person identified in such notice—

(I) compliance data for the establishment in accordance with clause (iii)(I); or

(II) information concerning the relationship between the owner or operator of the establishment and the accredited person identified in such notice in accordance with clause (iii)(II).

The owner or operator of the establishment, or such accredited person, as the case may be, shall respond to such a request not later than 60 days after receiving such request.

(iii)(I) The compliance data to be submitted by the owner or operator of a device establishment in response to a request under clause (ii)(I) are data describing whether the quality controls of the establishment have been sufficient for ensuring consistent compliance with current good manufacturing practice within the meaning of section 351(h) of this title and with other applicable provisions of this chapter. Such data shall include complete reports of inspectional findings regarding good manufacturing practice or other quality control audits that, during the preceding 2-year period, were conducted at the establishment by persons other than the owner or operator of the establishment, together with all other compliance data the Secretary deems necessary. Data under the preceding sentence shall demonstrate to the Secretary whether the establishment has facilitated consistent compliance by promptly correcting any compliance problems identified in such inspections.

(II) A request to an accredited person under clause (ii)(II) may not seek any information that is not required to be maintained by such person in records under subsection (f)(1).

(iv) A device establishment is deemed to have clearance to participate in the program and to use the accredited person identified in the notice under subparagraph (A)(ii) for inspections of the establishment unless the Secretary, not later than 60 days after receiving the information requested under clause (ii), issues a response that denies clearance to participate as provided under subparagraph (C).

(C)(i) The Secretary may deny clearance to a device establishment if the Secretary has evidence that the certification under subparagraph (A)(ii)(IV) is untrue and the Secretary provides to the owner or operator of the establishment a statement summarizing such evidence.

(ii) The Secretary may deny clearance to a device establishment if the Secretary determines that the establishment has failed to demonstrate consistent compliance for purposes of subparagraph (B)(iii)(I) and the Secretary provides to the owner or operator of the establishment a statement of the reasons for such determination.

(iii)(I) The Secretary may reject the selection of the accredited person identified in the notice under subparagraph (A)(ii) if the Secretary provides to the owner or operator of the establishment a statement of the reasons for such rejection. Reasons for the rejection may include that the establishment or the accredited person, as the case may be, has failed to fully respond to the request, or that the Secretary has concerns regarding the relationship between the establishment and such accredited person.

(II) If the Secretary rejects the selection of an accredited person by the owner or operator of a device establishment, the owner or operator may make an additional selection of an accredited person by submitting to the Secretary a notice that identifies the additional selection. Clauses (i) and (ii) of subparagraph (B), and subclause (I) of this clause, apply to the selection of an accredited person through a notice under the preceding sentence in the same manner and to the same extent as such provisions apply to a selection of an accredited person through a notice under subparagraph (A)(ii).

(iv) In the case of a device establishment that is denied clearance under clause (i) or (ii) or with respect to which the selection of the accredited person is rejected under clause (iii), the Secretary shall designate a person to review the statement of reasons, or statement summarizing such evidence, as the case may be, of the Secretary under such clause if, during the 30-day period beginning on the date on which the owner or operator of the establishment receives such statement, the owner or operator requests the review. The review shall commence not later than 30 days after the owner or operator requests the review, unless the Secretary and the owner or operator otherwise agree.

(7)(A) Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report in a form and manner designated by the Secretary to conduct inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.

(B) At a minimum, an inspection report under subparagraph (A) shall identify the persons responsible for good manufacturing practice compliance at the inspected device establishment, the dates of the inspection, the scope of the inspection, and shall describe in detail each observation identified by the accredited person, identify other matters that relate to or may influence compliance with this chapter, and describe any recommendations during the inspection or at the inspection's closing meeting.

(C) An inspection report under subparagraph (A) shall be sent to the Secretary and to the designated representative of the inspected device establishment at the same time, but under no circumstances later than three weeks after the last day of the inspection. The report to the Secretary shall be accompanied by all written inspection observations previously provided to the designated representative of the establishment.

(D) Any statement or representation made by an employee or agent of a device establishment to a person accredited under paragraph (2) to conduct inspections shall be subject to section 1001 of title 18.

(E) If at any time during an inspection by an accredited person the accredited person discovers a condition that could cause or contribute to an unreasonable risk to the public health, the accredited person shall immediately notify the Secretary of the identification of the device establishment subject to inspection and such condition.

(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality systems standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods.

(8) Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

(9) Nothing in this subsection affects the authority of the Secretary to inspect any device establishment pursuant to this chapter.

(10)(A) For fiscal year 2005 and each subsequent fiscal year, no device establishment may be inspected during the fiscal year involved by a person accredited under paragraph (2) if—

(i) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the preceding fiscal year (referred to in this subparagraph as the ''first prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such first prior fiscal year; and

(ii) of the amounts appropriated for salaries and expenses of the Food and Drug Administration for the fiscal year preceding the first prior fiscal year (referred to in this subparagraph as the ''second prior fiscal year''), the amount obligated by the Secretary for inspections of device establishments by the Secretary was less than the adjusted base amount applicable to such second prior fiscal year.

(B)(i) Subject to clause (ii), the Comptroller General of the United States shall determine the amount that was obligated by the Secretary for fiscal year 2002 for compliance activities of the Food and Drug Administration with respect to devices (referred to in this subparagraph as the ''compliance budget''), and of such amount, the amount that was obligated for inspections by the Secretary of device establishments (referred to in this subparagraph as the ''inspection budget'').

(ii) For purposes of determinations under clause (i), the Comptroller General shall not include in the compliance budget or the inspection budget any amounts obligated for inspections of device establishments conducted as part of the process of reviewing applications under section 360e of this title.

(iii) Not later than March 31, 2003, the Comptroller General shall complete the determinations required in this subparagraph and submit to the Secretary and the Congress a report describing the findings made through such determinations.

(C) For purposes of this paragraph:

(i) The term ''base amount'' means the inspection budget determined under subparagraph (B) for fiscal year 2002.

(ii) The term ''adjusted base amount'', in the case of applicability to fiscal year 2003, means an amount equal to the base amount increased by 5 percent.

(iii) The term ''adjusted base amount'', with respect to applicability to fiscal year 2004 or any subsequent fiscal year, means the adjusted base amount applicable to the preceding year increased by 5 percent.

(11) The authority provided by this subsection terminates on October 1, 2027.

(12) No later than four years after October 26, 2002, the Comptroller General shall report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor and Pensions of the Senate—

(A) the number of inspections conducted by accredited persons pursuant to this subsection and the number of inspections conducted by Federal employees pursuant to section 360(h) of this title and of device establishments required to register under section 360(i) of this title;

(B) the number of persons who sought accreditation under this subsection, as well as

the number of persons who were accredited under this subsection;

(C) the reasons why persons who sought accreditation, but were denied accreditation, were denied;

(D) the number of audits conducted by the Secretary of accredited persons, the quality of inspections conducted by accredited persons, whether accredited persons are meeting their obligations under this chapter, and whether the number of audits conducted is sufficient to permit these assessments;

(E) whether this subsection is achieving the goal of ensuring more information about device establishment compliance is being presented to the Secretary, and whether that information is of a quality consistent with information obtained by the Secretary pursuant to inspections conducted by Federal employees;

(F) whether this subsection is advancing efforts to allow device establishments to rely upon third-party inspections for purposes of compliance with the laws of foreign governments; and

(G) whether the Congress should continue, modify, or terminate the program under this subsection.

(13) The Secretary shall include in the annual report required under section 393(g) of this title the names of all accredited persons and the particular activities under this subsection for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

(14) Notwithstanding any provision of this subsection, this subsection does not have any legal effect on any agreement described in section 383(b) of this title between the Secretary and a foreign country.

(15)(A) Notwithstanding any other provision of this subsection, the Secretary may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization for purposes of conducting inspections of—

(i) establishments that manufacture, prepare, propagate, compound, or process devices (other than types of devices licensed under section 262 of title 42), as required under section 360(h) of this title; or

(ii) establishments required to register pursuant to section 360(i) of this title.

(B) Nothing in this paragraph affects—

(i) the authority of the Secretary to inspect any device establishment pursuant to this chapter; or

(ii) the authority of the Secretary to determine the official classification of an inspection.

(h) Improvements to inspections process for device establishments

(1) In the case of inspections other than for-cause inspections, the Secretary shall review processes and standards applicable to inspections of domestic and foreign device establishments in effect as of August 18, 2017, and update such processes and standards through the adoption of uniform processes and standards applicable to such inspections. Such uniform processes and standards shall provide for—

(A) exceptions to such processes and standards, as appropriate;

(B) announcing the inspection of the establishment within a reasonable time before such inspection occurs, including by providing to the owner, operator, or agent in charge of the establishment a notification regarding the type and nature of the inspection;

(C) a reasonable estimate of the timeframe for the inspection, an opportunity for advance communications between the officers or employees carrying out the inspection under subsection (a)(1) and the owner, operator, or agent in charge of the establishment concerning appropriate working hours during the inspection, and, to the extent feasible, advance notice of some records that will be requested; and

(D) regular communications during the inspection with the owner, operator, or agent in charge of the establishment regarding inspection status, which may be recorded by either party with advance notice and mutual consent.

(2)(A) The Secretary shall, with respect to a request described in subparagraph (B), provide nonbinding feedback with respect to such request not later than 45 days after the Secretary receives such request.

(B) A request described in this subparagraph is a request for feedback—

(i) that is made by the owner, operator, or agent in charge of such establishment in a timely manner; and

(ii) with respect to actions proposed to be taken by a device establishment in a response to a report received by such establishment pursuant to subsection (b) that involve a public health priority, that implicate systemic or major actions, or relate to emerging safety issues (as determined by the Secretary).

(3) Nothing in this subsection affects the authority of the Secretary to conduct inspections otherwise permitted under this chapter in order to ensure compliance with this chapter.

(June 25, 1938, ch. 675, § 704, 52 Stat. 1057; Aug. 7, 1953, ch. 350, § 1, 67 Stat. 476; Pub. L. 87–781, title II, § 201(a), (b), Oct. 10, 1962, 76 Stat. 792, 793; Pub. L. 94–295, § 6, May 28, 1976, 90 Stat. 581; Pub. L. 96–359, § 4, Sept. 26, 1980, 94 Stat. 1193; Pub. L. 103–80, § 3(aa), Aug. 13, 1993, 107 Stat. 778; Pub. L. 105–115, title I, § 125(b)(2)(L), title II, § 210(b), title IV, § 412(b), Nov. 21, 1997, 111 Stat. 2326, 2344, 2375; Pub. L. 107–188, title III, § 306(b), June 12, 2002, 116 Stat. 670; Pub. L. 107–250, title II, § 201(a), (b), Oct. 26, 2002, 116 Stat. 1602, 1609; Pub. L. 108–214, § 2(b)(1), Apr. 1, 2004, 118 Stat. 573; Pub. L. 110–85, title II, § 228, Sept. 27, 2007, 121 Stat. 855; Pub. L. 111–31, div. A, title I, § 103(i), June 22, 2009, 123 Stat. 1837; Pub. L. 111–353, title I, § 101(b), Jan. 4, 2011, 124 Stat. 3887; Pub. L. 112–144, title VI, § 612, title VII, § 706, July 9, 2012, 126 Stat. 1060, 1067; Pub. L. 115–52, title VII, §§ 702(a), 703, 705, Aug. 18, 2017, 131 Stat. 1055–1057; Pub. L. 116–136, div. A, title III, § 3112(d), Mar. 27, 2020, 134 Stat. 362; Pub. L. 117–180, div. F, title V, § 5007, Sept. 30, 2022, 136 Stat. 2168; Pub. L. 117–229, div. C, title III, § 306, Dec. 16, 2022, 136 Stat. 2312; Pub. L. 117–328, div. FF, title II, § 2515(a)(2), title III, §§ 3106, 3504, 3611(a), (b)(1), 3612(a), 3613(b), Dec. 29, 2022, 136 Stat. 5806, 5807, 5859, 5869, 5872.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (a)(5), 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.

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, § 3611(a), substituted ''devices'' for ''restricted devices'' in two places.

Pub. L. 117–328, § 3504, inserted ''In the case of a facility (as defined in section 364 of this title) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 364a, 364b, and 364f of this title, when the standard for records inspection under such section applies.'' after ''limitations established in section 350c(d) of this title.''

Subsec. (a)(4)(A). Pub. L. 117–328, § 3611(b)(1), substituted ''an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device, or a site or facility that is subject to inspection under paragraph (5)(C),'' for ''an establishment that is engaged in the manufacture, preparation, propagation, compounding, or processing of a drug'' and ''records or other information requested and a rationale for requesting such records or other information in advance of, or in lieu of, an inspection.'' for ''records requested.''

Subsec. (a)(4)(C), (D). Pub. L. 117–328, § 3613(b), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (a)(5). Pub. L. 117–328, § 3612(a), added par. (5).

Subsec. (b). Pub. L. 117–328, § 2515(a)(2), made technical amendment to directory language of Pub. L. 116–136, § 3112(d)(1). See 2020 Amendment note below.

Subsec. (g)(11). Pub. L. 117–328, § 3106, substituted ''October 1, 2027'' for ''December 24, 2022''.

Pub. L. 117–229 substituted ''December 24, 2022'' for ''December 17, 2022''.

Pub. L. 117–180 substituted ''December 17'' for ''October 1''.

2020—Subsec. (b). Pub. L. 116–136, § 3112(d)(1), as amended by Pub. L. 117–328, § 2515(a)(2), designated existing provisions as par. (1), redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), and added par. (2).

2017—Subsec. (g)(11). Pub. L. 115–52, § 703, substituted ''October 1, 2022'' for ''October 1, 2017''.

Subsec. (g)(15). Pub. L. 115–52, § 705, added par. (15).

Subsec. (h). Pub. L. 115–52, § 702(a), added subsec. (h).

2012—Subsec. (a)(4). Pub. L. 112–144, § 706, added par. (4).

Subsec. (g)(11). Pub. L. 112–144, § 612, substituted ''October 1, 2017'' for ''October 1, 2012''.

2011—Subsec. (a)(1). Pub. L. 111–353, which directed the amendment of subsec. (a)(1)(B) by substituting ''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'' for ''section 350c of this title when'' and all that follows through ''subject to'', was executed by making the substitution for ''section 350c of this title when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to'' in the sentence following subpar. (B) of subsec. (a)(1), to reflect the probable intent of Congress.

2009—Subsec. (a)(1). Pub. L. 111–31, § 103(i)(1)(C), substituted ''devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) of this title, section 360i of this title, section 360j(g) of this title, or subchapter IX and data relating to other drugs, devices, or tobacco products'' for ''and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) section 360i, or 360j(g) of this title, and data relating to other drugs or devices''.

Pub. L. 111–31, § 103(i)(1)(B), substituted ''restricted devices, or tobacco products'' for ''or restricted devices'' in two places.

Subsec. (a)(1)(A). Pub. L. 111–31, § 103(i)(1)(A), substituted ''devices, tobacco products, or cosmetics'' for ''devices, or cosmetics'' in two places.

Subsec. (b). Pub. L. 111–31, § 103(i)(2), inserted ''tobacco product,'' after ''device,''.

Subsec. (g)(13). Pub. L. 111–31, § 103(i)(3), made technical amendment to reference in original act which appears in text as reference to section 393(g) of this title.

2007—Subsec. (g)(1). Pub. L. 110–85, § 228(1), substituted ''The Secretary'' for ''Not later than one year after October 26, 2002, the Secretary''.

Subsec. (g)(2). Pub. L. 110–85, § 228(2), substituted ''The Secretary'' for ''Not later than 180 days after October 26, 2002, the Secretary'' and struck out at end ''In the first year following the publication in the Federal Register of criteria to accredit or deny accreditation to persons who request to perform the duties specified in paragraph (1), the Secretary shall accredit no more than 15 persons who request to perform duties specified in paragraph (1).''

Subsec. (g)(3)(F), (G). Pub. L. 110–85, § 228(3), added subpars. (F) and (G).

Subsec. (g)(6). Pub. L. 110–85, § 228(4), amended par. (6) generally, revising and restating provisions of former subpars. (A) to (C).

Subsec. (g)(7)(A). Pub. L. 110–85, § 228(5)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: ''Persons accredited under paragraph (2) to conduct inspections shall record in writing their inspection observations and shall present the observations to the device establishment's designated representative and describe each observation. Additionally, such accredited person shall prepare an inspection report (including for inspections classified as 'no action indicated') in a form and manner consistent with such reports prepared by employees and officials designated by the Secretary to conduct inspections.''

Subsec. (g)(7)(F). Pub. L. 110–85, § 228(5)(B), added subpar. (F).

Subsec. (g)(10)(C)(iii). Pub. L. 110–85, § 228(6), substituted ''base amount applicable'' for ''based amount applicable''.

2004—Subsec. (g)(1). Pub. L. 108–214, § 2(b)(1)(A), in first sentence, substituted ''conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices, which inspections are required under section 360(h) of this title or are inspections of such establishments required to register under section 360(i) of this title.'' for ''conducting inspections of establishments that manufacture, prepare, propagate, compound, or process class II or class III devices that are required in section 360(h) of this title, or inspections of such establishments required to register pursuant to section 360(i) of this title.''

Subsec. (g)(5)(B). Pub. L. 108–214, § 2(b)(1)(B), in first sentence, substituted ''poses a threat to public health, fails to act in a manner that is consistent with the purposes of this subsection, or where the Secretary determines that there is a financial conflict of interest in the relationship between the accredited person and the owner or operator of a device establishment that the accredited person has inspected under this subsection.'' for ''or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this subsection.''

Subsec. (g)(6)(A)(i). Pub. L. 108–214, § 2(b)(1)(C)(i), substituted ''described in paragraph (1)'' for ''of the establishment pursuant to subsection (h) or (i) of section 360 of this title''.

Subsec. (g)(6)(A)(ii). Pub. L. 108–214, § 2(b)(1)(C)(ii)(I), substituted ''inspections'' for ''each inspection'' and inserted ''during a 2-year period'' after ''person'' in introductory provisions.

Subsec. (g)(6)(A)(ii)(I). Pub. L. 108–214, § 2(b)(1)(C)(ii)(II), substituted ''an accredited person'' for ''such a person''.

Subsec. (g)(6)(A)(iii). Pub. L. 108–214, § 2(b)(1)(C)(iii)(I), substituted ''and 1 or both of the following additional conditions are met:'' for ''and the following additional conditions are met:'' in introductory provisions.

Subsec. (g)(6)(A)(iii)(I). Pub. L. 108–214, § 2(b)(1)(C)(iii)(II), substituted ''(accredited under paragraph (2) and identified under clause (ii)(II)) as a person authorized to conduct such inspections of device establishments.'' for ''accredited under paragraph (2) and identified under subclause (II) of this clause.''

Subsec. (g)(6)(A)(iii)(II). Pub. L. 108–214, § 2(b)(1)(C)(iii)(III), inserted ''or by a person accredited under paragraph (2)'' after ''by the Secretary''.

Subsec. (g)(6)(A)(iv)(I). Pub. L. 108–214, § 2(b)(1)(C)(iv), in first sentence, inserted ''section'' after ''pursuant to'' and substituted ''inspections of the establishment during the previous 4 years'' for ''the two immediately preceding inspections of the establishment'', in third sentence, struck out ''the petition states a commercial reason for the waiver;'' after ''granted only if'' and inserted ''not'' after ''the Secretary has not determined that the public health would'', and, in last sentence, substituted ''granted or deemed to be granted until'' for ''granted until''.

Subsec. (g)(6)(A)(iv)(II). Pub. L. 108–214, § 2(b)(1)(C)(v), inserted ''of a device establishment required to register'' after ''to be conducted'' and ''section'' after ''pursuant to''.

Subsec. (g)(6)(B)(iii). Pub. L. 108–214, § 2(b)(1)(D), in first sentence, substituted ''and with other'' for '', and data otherwise describing whether the establishment has consistently been in compliance with sections 351 and 352 of this title and other'' and, in second sentence, substituted ''inspectional findings'' for ''inspections'' and inserted ''relevant'' after ''together with all other''.

Subsec. (g)(6)(B)(iv). Pub. L. 108–214, § 2(b)(1)(E), designated existing provisions as subcl. (I) and added subcl. (II).

Subsec. (g)(6)(C)(ii). Pub. L. 108–214, § 2(b)(1)(F), struck out ''in accordance with section 360(h) of this title, or has not during such period been inspected pursuant to section 360(i) of this title, as applicable'' after ''inspected by the Secretary''.

Subsec. (g)(10)(B)(iii). Pub. L. 108–214, § 2(b)(1)(G), substituted ''a report'' for ''a reporting''.

Subsec. (g)(12)(A). Pub. L. 108–214, § 2(b)(1)(H)(i), added subpar. (A) and struck out former subpar. (A) which read as follows: ''the number of inspections pursuant to subsections (h) and (i) of section 360 of this title conducted by accredited persons and the number of inspections pursuant to such subsections conducted by Federal employees;''.

Subsec. (g)(12)(E). Pub. L. 108–214, § 2(b)(1)(H)(ii), substituted ''obtained by the Secretary pursuant to inspections conducted by Federal employees;'' for ''obtained by the Secretary pursuant to subsection (h) or (i) of section 360 of this title;''.

2002—Subsec. (a)(1). Pub. L. 107–188, § 306(b)(1), inserted after first sentence ''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 Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 350c(d) of this title.''

Subsec. (a)(2). Pub. L. 107–188, § 306(b)(2), substituted ''third sentence'' for ''second sentence'' in introductory provisions.

Subsec. (f)(1). Pub. L. 107–250, § 201(b)(1), in first sentence, substituted ''An accredited person described in paragraph (3) shall maintain records'' for ''A person accredited under section 360m of this title to review reports made under section 360(k) of this title and make recommendations of initial classifications of devices to the Secretary shall maintain records''.

Subsec. (f)(2). Pub. L. 107–250, § 201(b)(2), substituted ''an accredited person described in paragraph (3)'' for ''a person accredited under section 360m of this title''.

Subsec. (f)(3). Pub. L. 107–250, § 201(b)(3), added par. (3).

Subsec. (g). Pub. L. 107–250, § 201(a), added subsec. (g).

1997—Subsec. (a)(1). Pub. L. 105–115, § 412(b), substituted ''prescription drugs, nonprescription drugs intended for human use,'' for ''prescription drugs'' in two places.

Pub. L. 105–115, § 125(b)(2)(L), struck out '', section 357(d) or (g),'' before ''section 360i''.

Subsec. (f). Pub. L. 105–115, § 210(b), added subsec. (f).

1993—Subsec. (a)(1). Pub. L. 103–80 substituted a comma for semicolon after ''finished and unfinished materials'' and ''section 355(i) or (k)'' for ''section 355(i) or (j)''.

1980—Subsec. (a)(1). Pub. L. 96–359, § 4(1), (2), restructured first five sentences of former subsec. (a) as par. (1) and, as so restructured, inserted reference to paragraph (3) and substituted ''(A)'' and ''(B)'' for ''(1)'' and ''(2)'', respectively.

Subsec. (a)(2). Pub. L. 96–359, § 4(3), redesignated sixth sentence of former subsec. (a) as par. (2) and, as so redesignated, substituted reference to second sentence of paragraph (1) for reference to former second sentence of this subsection, and ''(A)'', ''(B)'', ''(C)'', and ''(D)'', for ''(1)'', ''(2)'', ''(3)'', and ''(4)'', respectively.

Subsec. (a)(3). Pub. L. 96–359, § 4(4), added par. (3).

1976—Subsec. (a). Pub. L. 94–295, § 6(a)–(c), expanded existing provisions to encompass medical devices by inserting references to factories, warehouses, establishments, and consulting laboratories in which restricted devices are manufactured, processed, packed, or held, inspections relating to devices, reporting and inspection regulations issued pursuant to sections 360i and 360j(g) of this title, and the manufacture and processing of devices.

Subsec. (e). Pub. L. 94–295, § 6(d), added subsec. (e).

1962—Subsec. (a). Pub. L. 87–781, § 201(a), extended the inspection, where prescription drugs are manufactured, processed, packed, or held, to all things bearing on whether adulterated or misbranded drugs, or any which may not be manufactured, introduced in interstate commerce, or sold or offered for sale under any provision of this chapter, have been or are being manufactured, processed, packed, transported or held in any such place, or otherwise bearing on violation of this chapter, but excluded from such inspection, data concerning finance, sales other than shipment, pricing, personnel other than qualifications of technical and professional personnel, research other than relating to new drugs subject to reporting, provided that provisions of second sentence of this subsection shall be inapplicable to pharmacies, practitioners and other persons enumerated in pars. (1) to (4), and struck out ''are held'' before ''after such introduction''.

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).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2020 AMENDMENT

Amendment by Pub. L. 116–136 effective 180 days after Mar. 27, 2020, see section 3112(g) of Pub. L. 116–136, set out as a note under section 356c of this title.

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.

REVIEW OF PROCESSES AND PRACTICES; GUIDANCE FOR INDUSTRY

Pub. L. 117–328, div. FF, title III, §3612(b), Dec. 29, 2022, 136 Stat. 5871, provided that:

''(1) IN GENERAL.—The Secretary [of Health and Human Services] shall—

''(A) review processes and practices in effect as of the date of enactment of this Act [Dec. 29, 2022] applicable to inspections of foreign and domestic sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374(a)(5)], as added by subsection (a); and

''(B) evaluate whether any updates are needed to facilitate the consistency of such processes and practices.

''(2) GUIDANCE.—

''(A) IN GENERAL.—The Secretary shall issue guidance describing the processes and practices applicable to inspections of sites and facilities described in subparagraph (C)(i) of section 704(a)(5) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), including with respect to the types of records and information required to be provided, best practices for communication between the Food and Drug Administration and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct, to the extent not specified in existing publicly available Food and Drug Administration guides and manuals for such inspections.

''(B) TIMING.—The Secretary shall—

''(i) not later than 18 months after the date of enactment of this Act, issue draft guidance under subparagraph (A); and

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

UNANNOUNCED FOREIGN FACILITY INSPECTIONS PILOT PROGRAM

Pub. L. 117–328, div. FF, title III, §3615, Dec. 29, 2022, 136 Stat. 5873, provided that:

''(a) IN GENERAL.—The Secretary [of Health and Human Services] shall conduct a pilot program under which the Secretary increases the conduct of unannounced surveillance inspections of foreign human drug establishments and evaluates the differences between such inspections of domestic and foreign human drug establishments, including the impact of announcing inspections to persons who own or operate foreign human drug establishments in advance of an inspection. Such pilot program shall evaluate—

''(1) differences in the number and type of violations of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)) identified as a result of unannounced and announced inspections of foreign human drug establishments and any other significant differences between each type of inspection;

''(2) costs and benefits associated with conducting announced and unannounced inspections of foreign human drug establishments;

''(3) barriers to conducting unannounced inspections of foreign human drug establishments and any challenges to achieving parity between domestic and foreign human drug establishment inspections; and

''(4) approaches for mitigating any negative effects of conducting announced inspections of foreign human drug establishments.

''(b) PILOT PROGRAM SCOPE.—The inspections evaluated under the pilot program under this section shall be routine surveillance inspections and shall not include inspections conducted as part of the Secretary's evaluation of a request for approval to market a drug submitted under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or the Public Health Service Act (42 U.S.C. 201 et seq.).

''(c) PILOT PROGRAM INITIATION.—The Secretary shall initiate the pilot program under this section not later than 180 days after the date of enactment of this Act [Dec. 29, 2022].

''(d) REPORT.—The Secretary shall, not later than 180 days following the completion of the pilot program under this section, make available on the website of the Food and Drug Administration a final report on the pilot program under this section, including—

''(1) findings and any associated recommendations with respect to the evaluation under subsection (a), including any recommendations to address identified barriers to conducting unannounced inspections of foreign human drug establishments;

''(2) findings and any associated recommendations regarding how the Secretary may achieve parity between domestic and foreign human drug inspections; and

''(3) the number of unannounced inspections during the pilot program that would not be unannounced under practices in use as of the date of the enactment of this Act.''

GUIDANCE

Pub. L. 117–328, div. FF, title III, §3611(b)(2), Dec. 29, 2022, 136 Stat. 5869, provided that:

''(A) IN GENERAL.—The Secretary [of Health and Human Services] shall issue or update guidance describing—

''(i) circumstances in which the Secretary intends to issue requests for records or other information in advance of, or in lieu of, an inspection under section 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