
21 U.S. Code § 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 inspection 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.

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