(h) Limitations

(1) No effect on section 374 inspections

The audits performed under this section shall not be considered inspections under section 374 of this title.

(2) No effect on inspection authority

Nothing in this section affects the authority of the Secretary to inspect any eligible entity pursuant to this chapter.

(June 25, 1938, ch. 675, § 808, as added Pub. L. 111–353, title III, § 307, Jan. 4, 2011, 124 Stat. 3959.)

Editorial Notes

REFERENCES IN TEXT

Section 381(q) of this title, referred to in subsec. (c)(2)(C)(ii), was in the original ''301(g)'', and was translated as reading ''801(q)'', meaning section 801(q) of act June 25, 1938, ch. 675, which is classified to section 381(q) of this title, to reflect the probable intent of Congress, because section 381(q) of this title relates to food certification, whereas section 301(g) of act June 25, 1938, ch. 675, which is classified to section 331(g) of this title, does not relate to food certification.

Section 1622(h) of title 7, referred to in subsec. (c)(8), was in the original ''section 203(h) of the Agriculture Marketing Act of 1946'', and was translated as reading ''section 203(h) of the Agricultural Marketing Act of 1946'', meaning section 203(h) of act Aug. 14, 1946, ch. 966, which is classified to section 1622(h) of Title 7, Agriculture, to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

CONSTRUCTION

Nothing in this section 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.

§ 384e. Recognition of foreign government inspections

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 360(i) of this title in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 360(h) of this title;

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this chapter; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this chapter.

(b) Results of inspection

The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

(1) evidence of compliance with section 351(a)(2)(B) of this title or section 381(r) of this title; and

(2) for any other purposes as determined appropriate by the Secretary.

(c) Periodic review

(1) In general

Beginning not later than 1 year after December 29, 2022, the Secretary shall periodically assess whether additional arrangements and agreements with a foreign government or an agency of a foreign government, as allowed under this section, are appropriate.

(2) Reports to Congress

Beginning not later than 4 years after December 29, 2022, and every 4 years thereafter, the Secretary shall submit 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 report describing the findings and conclusions of each review conducted under paragraph (1).

(June 25, 1938, ch. 675, § 809, as added Pub. L. 112–144, title VII, § 712, July 9, 2012, 126 Stat. 1072; amended Pub. L. 114–255, div. A, title III, § 3101(a)(2)(X), Dec. 13, 2016, 130 Stat. 1156; Pub. L. 115–52, title VII, § 701(b), Aug. 18, 2017, 131 Stat. 1055; Pub. L. 117–328, div. FF, title III, § 3613(c), Dec. 29, 2022, 136 Stat. 5872.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117–328, § 3613(c)(1), inserted ''preapproval or'' before ''risk-based inspections''.

Subsec. (c). Pub. L. 117–328, § 3613(c)(2), added subsec. (c).

2017—Subsec. (a)(1). Pub. L. 115–52 substituted ''paragraph (2) or (3) of section 360(h)'' for ''section 360(h)(3)''.

2016—Subsec. (a)(2). Pub. L. 114–255 substituted ''conducting'' for ''conduction''.

§ 384f. Strengthening FDA and CBP coordination and capacity

(a) In general

The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall coordinate with the Secretary of Homeland Security to carry out activities related to customs and border protection and in response to illegal controlled substances and drug imports, including at sites of import (such as international mail facilities), that will provide improvements to such facilities, technologies, and inspection capacity. Such Secretaries may carry out such activities through a memorandum of understanding between the Food and Drug Administration and the U.S. Customs and Border Protection.

(b) FDA import facilities and inspection capacity

(1) In general

In carrying out this section, the Secretary shall, in collaboration with the Secretary of