

(10) sue and be sued in its corporate name, and complain and defend in courts of competent jurisdiction;

(11) appoint other groups of advisors as may be determined necessary to carry out the functions of the Foundation; and

(12) exercise other powers as set forth in this section, and such other incidental powers as are necessary to carry out its powers, duties, and functions in accordance with this part.

(i) Acceptance of funds from other sources

The Executive Director may solicit and accept on behalf of the Foundation, any funds, gifts, grants, devises, or bequests of real or personal property made to the Foundation, including from private entities, for the purposes of carrying out the duties of the Foundation.

(j) Service of Federal employees

Federal Government employees may serve on committees advisory to the Foundation and otherwise cooperate with and assist the Foundation in carrying out its functions, so long as such employees do not direct or control Foundation activities.

(k) Detail of Government employees; fellowships

(1) Detail from Federal agencies

Federal Government employees may be detailed from Federal agencies with or without reimbursement to those agencies to the Foundation at any time, and such detail shall be without interruption or loss of civil service status or privilege. Each such employee shall abide by the statutory, regulatory, ethical, and procedural standards applicable to the employees of the agency from which such employee is detailed and those of the Foundation.

(2) Voluntary service; acceptance of Federal employees

(A) Foundation

The Executive Director of the Foundation may accept the services of employees detailed from Federal agencies with or without reimbursement to those agencies.

(B) Food and Drug Administration

The Commissioner may accept the uncompensated services of Foundation fellows or trainees. Such services shall be considered to be undertaking an activity under contract with the Secretary as described in section 379 of this title.

(l) Annual reports

(1) Reports to Foundation

Any recipient of a grant, contract, fellowship, memorandum of understanding, or cooperative agreement from the Foundation under this section shall submit to the Foundation a report on an annual basis for the duration of such grant, contract, fellowship, memorandum of understanding, or cooperative agreement, that describes the activities carried out under such grant, contract, fellowship, memorandum of understanding, or cooperative agreement.

(2) Report to Congress and the FDA

Beginning with fiscal year 2009, the Executive Director shall submit to Congress and the Commissioner an annual report that—

(A) describes the activities of the Foundation and the progress of the Foundation in furthering the goals and priorities established under subsection (c)(2), including the practical impact of the Foundation on regulated product development;

(B) provides a specific accounting of the source and use of all funds used by the Foundation to carry out such activities; and

(C) provides information on how the results of Foundation activities could be incorporated into the regulatory and product review activities of the Food and Drug Administration.

(m) Separation of funds

The Executive Director shall ensure that the funds received from the Treasury are managed as individual programmatic funds under subsection (i), according to best accounting practices.

(n) Funding

From amounts appropriated to the Food and Drug Administration for each fiscal year, the Commissioner shall transfer not less than \$1,250,000 and not more than \$5,000,000, to the Foundation to carry out subsections (a), (b), and (d) through (m).

(June 25, 1938, ch. 675, § 770, as added Pub. L. 110–85, title VI, § 601(a), Sept. 27, 2007, 121 Stat. 890; amended Pub. L. 114–255, div. A, title III, § 3076, Dec. 13, 2016, 130 Stat. 1139; Pub. L. 117–101, § 2(a), Mar. 15, 2022, 136 Stat. 47.)

Editorial Notes

AMENDMENTS

2022—Subsec. (n). Pub. L. 117–101 substituted “\$1,250,000 and not more than \$5,000,000” for “\$500,000 and not more than \$1,250,000”.

2016—Subsec. (d)(1)(C)(ii). Pub. L. 114–255, § 3076(a)(1)(B), added cl. (ii). Former cl. (ii) redesignated (iii).

Subsec. (d)(1)(C)(iii). Pub. L. 114–255, § 3076(a)(1)(A), redesignated cl. (ii) as (iii).

Subsec. (d)(1)(C)(iii)(I). Pub. L. 114–255, § 3076(a)(1)(C), substituted “The ex officio members, acting pursuant to clause (i), and the Board, acting pursuant to clause (ii), shall ensure” for “The ex officio members shall ensure”.

Subsec. (d)(1)(C)(iii)(II). Pub. L. 114–255, § 3076(a)(2), inserted at end “For purposes of this section, the term ‘employee of the Federal Government’ does not include a special Government employee, as that term is defined in section 202(a) of title 18.”

Subsec. (d)(3)(A). Pub. L. 114–255, § 3076(a)(3), amended subpar. (A) generally. Prior to amendment, text read as follows: “The term of office of each member of the Board appointed under paragraph (1)(C) shall be 4 years, except that the terms of offices for the initial appointed members of the Board shall expire on a staggered basis as determined by the ex officio members.”

Subsec. (g)(2). Pub. L. 114–255, § 3076(b), struck out before period at end “but shall not be greater than the compensation of the Commissioner”.

Subsec. (m). Pub. L. 114–255, § 3076(c), substituted “are managed as individual programmatic funds under subsection (i), according to best accounting practices” for “are held in separate accounts from funds received from entities under subsection (i)”.

§ 379dd–1. Location of Foundation

The Foundation shall, if practicable, be located not more than 20 miles from the District of Columbia.

(June 25, 1938, ch. 675, §771, as added Pub. L. 110-85, title VI, §601(b), Sept. 27, 2007, 121 Stat. 897.)

§ 379dd-2. Activities of the Food and Drug Administration

(a) In general

The Commissioner shall receive and assess the report submitted to the Commissioner by the Executive Director of the Foundation under section 379dd(l)(2) of this title.

(b) Report to Congress

Beginning with fiscal year 2009, the Commissioner shall submit to Congress an annual report summarizing the incorporation of the information provided by the Foundation in the report described under section 379dd(l)(2) of this title and by other recipients of grants, contracts, memoranda of understanding, or cooperative agreements into regulatory and product review activities of the Food and Drug Administration.

(c) Extramural grants

The provisions of this part and section 360bbb-5 of this title shall have no effect on any grant, contract, memorandum of understanding, or cooperative agreement between the Food and Drug Administration and any other entity entered into before, on, or after September 27, 2007.

(June 25, 1938, ch. 675, §772, as added Pub. L. 110-85, title VI, §601(b), Sept. 27, 2007, 121 Stat. 897.)

SUBCHAPTER VIII—IMPORTS AND EXPORTS

§ 381. Imports and exports

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 360 or section 387e(h) of this title and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the meth-

ods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 360j(f) of this title, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 355 of this title or the importer (as defined in section 384a of this title) is in violation of such section 384a of this title, or prohibited from introduction or delivery for introduction into interstate commerce under section 331(l) of this title, or is a controlled substance subject to an order under section 360bbb-8d of this title, or (4) the recordkeeping requirements under section 2223 of this title (other than the requirements under subsection (f) of such section) have not been complied with regarding such article or¹ (5) such article is being imported or offered for import in violation of section 331(cc) of this title, then any such article described in any of clauses (1) through (5) shall be refused admission, except as provided in subsection (b) of this section. If it appears from the examination of such samples or otherwise that the article is a counterfeit drug or counterfeit device, such article shall be refused admission. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission. If such article is subject to a requirement under section 364a, 379aa, or 379aa-1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in section 364, 379aa, or 379aa-1 of this title) has not complied with a requirement of such section 364a, 379aa, or 379aa-1 of this title with respect to any such article, or has not allowed access to records described in such section 364a, 379aa, or 379aa-1 of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations, except that the Secretary of Health and Human Services may destroy, without the opportunity for export, any drug or device refused admission under this section, if such drug or device is valued at an amount that is \$2,500 or less (or such higher amount as the Secretary of the Treasury may set by regulation pursuant to section 1498(a)(1) of title 19) and was not brought into compliance as described under subsection (b). The Secretary of Health and Human Services shall issue regulations providing for notice and an opportunity to appear before the Secretary of Health and Human Services and introduce testimony, as described in the first sentence of this subsection, on destruction of a drug or device under the seventh sentence of this subsection. The regula-

¹ So in original. Probably should be preceded by a comma.