

§ 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, 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 of this title and shall request that if any drugs and devices 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 and devices 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 methods 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 prohibited from introduction or delivery for introduction into interstate commerce under section 331(l) of this title, then such article shall be refused admission, except as provided in subsection (b) of this section. If such article is subject to a requirement under section 379aa or 379aa-1 of this title and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 379aa or 379aa-1 of this title) has not complied with a requirement of such section 379aa or 379aa-1 of this title with respect to any such article, or has not allowed access to records described in such section 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 ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph¹ shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act [21 U.S.C. 951 et seq.].

(b) Disposition of refused articles

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that (1) an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with this chapter or rendered other than a food, drug, device, or cosmetic, or (2) with respect to an article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 379aa or 379aa-1 of this title) can take action that would assure that the responsible person is in compliance with section 379aa or 379aa-1 of this title, as the case may be, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, or, with respect to clause (2), the responsible person, to perform such relabeling or other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant to such authorization

¹ So in original. Probably should be "subsection".