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# 21 U.S. Code § 381

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## Imports and exports

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### **(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 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 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 or <sup>[1]</sup>(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 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 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 regulations shall provide that prior to destruction, appropriate due process is available to the owner or consignee seeking to challenge the decision to destroy the drug or device. Where the Secretary of Health and Human Services provides notice and an opportunity to appear and introduce testimony on the destruction of a drug or device, the Secretary of Health and Human Services shall store and, as applicable, dispose of the drug or device after the issuance of the notice, except that the owner and consignee shall remain liable for costs pursuant to subsection (c). Such process may be combined with the notice and opportunity to appear before the Secretary and introduce testimony, as described in the first sentence of this subsection, as long as appropriate notice is provided to the owner or consignee. Neither clause (2) nor clause (5) of the third sentence of this subsection shall 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.].

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