

Food and Drug Administration, HHS

§ 1.94

medical devices that received pre-market clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act; or the Humanitarian Device Exemption Number for those medical devices for which an exemption has been granted under section 520(m) of the Federal Food, Drug, and Cosmetic Act.

(j) *Medical device component.* If applicable for a medical device, an affirmation identifying that the article being imported or offered for import is a component that requires further processing or inclusion into a finished medical device.

[81 FR 85870, Nov. 29, 2016, as amended at 86 FR 17060, Apr. 1, 2021]

§ 1.79 Tobacco products.

In addition to the data required to be submitted in § 1.72, an ACE filer must submit the following information at the time of filing entry in ACE.

(a) *Brand name* of an article that is a tobacco product that is being imported or offered for import. If the article does not have a specific brand name, the ACE filer must submit a commercial name for the brand name. This data element is not applicable to those products solely intended either for further manufacturing or as investigational tobacco products.

(b) [Reserved]

§ 1.80 Cosmetics.

An ACE filer must submit the data specified in § 1.72 at the time of filing entry in ACE.

§ 1.81 Rejection of entry filing.

FDA may reject an entry filing for failure to provide complete and accurate information that is required pursuant to this subpart.

Subpart E—Imports and Exports

§ 1.83 Definitions.

For the purposes of regulations prescribed under section 801(a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term *owner* or *consignee* means the person who makes entry under the provisions of section 484 of the Tariff Act of 1930, as amended (19

U.S.C. 1484), namely, the “importer of record.”

(b) The term *division director* means the director of the division of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the division as he or she may designate to act on his or her behalf in administering and enforcing the provisions of section 801(a), (b), and (c).

[42 FR 15553, Mar. 22, 1977, as amended at 81 FR 85872, Nov. 29, 2016; 85 FR 50781, Aug. 18, 2020]

§ 1.90 Notice of sampling.

When a sample of an article offered for import has been requested by the division director, FDA shall provide to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the division director or U.S. Customs and Border Protection of the results of examination of the sample.

[85 FR 50781, Aug. 18, 2020]

§ 1.91 Payment for samples.

The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration division where the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in § 1.95.

[42 FR 15553, Mar. 22, 1977, as amended at 85 FR 50781, Aug. 18, 2020]

§ 1.94 Hearing on refusal of admission or destruction.

(a) If it appears that the article may be subject to refusal of admission or that the article is a drug that may be subject to destruction under section