medical devices that received premarket 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 mended 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

801(a) of the Federal Food, Drug, and Cosmetic Act, the division director shall give the owner or consignee a written or electronic notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility or destruction of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his or her intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing on refusal of admission, the division director shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

(c) If the article is a drug that may be subject to destruction under section 801(a) of the Federal Food, Drug, and Cosmetic Act, the division director may give the owner or consignee a single written or electronic notice that provides the notice of refusal of admission and the notice of destruction of an article described in paragraph (a) of this section. The division director may also combine the hearing on refusal of admission with the hearing on destruction of the article described in paragraph (a) of this section into a single proceeding.

[80 FR 55242, Sept. 15, 2015, as amended at 81 FR 85873, Nov. 29, 2016; 85 FR 50781, Aug. 18, 2020]

§ 1.95 Application for authorization to relabel and recondition.

Application for authorization to relabel or perform other action to bring the article into compliance with the Federal Food, Drug, and Cosmetic Act or to render it other than a food, drug, device, or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

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

§ 1.96 Granting of authorization to relabel and recondition.

(a) When authorization of a proposal under §1.95 is granted by the division director, the applicant shall be notified of authorization, in writing, which may include:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or U.S. Customs and Border Protection, as appropriate;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the division director may grant such additional time as he or she deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the division director.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond with U.S. Customs and Border Protection and obtained a new authorization from the Food and Drug Administration division director. Any authorization granted under this section shall supersede and nullify any previously