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taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under §1004.1 in a manner designed to encourage the public to respond to the proposal, the Secretary will send written notice of his approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Secretary deems necessary to protect the public health and safety. Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

[38 FR 28629, Oct. 15, 1973, as amended at 41 FR 48269, Nov. 2, 1976; 42 FR 15676, Mar. 22, 1977]

PART 1005—IMPORTATION OF ELECTRONIC PRODUCTS

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AUTHORITY: 21 U.S.C. 360ii, 360mm.

SOURCE: 38 FR 28630, Oct. 15, 1973, unless otherwise noted.

Subpart A—General Provisions

§ 1005.1 Applicability.

(a) The provisions of §§1005.1 through 1005.24 are applicable to electronic products which are subject to the standards prescribed under this subchapter and are offered for importation into the United States.

(b) Section 1005.25 is applicable to every manufacturer of electronic products offering an electronic product for importation into the United States.

[38 FR 28630, Oct. 15, 1973, as amended at 45 FR 81739, Dec. 12, 1980]

§ 1005.2 Definitions.

As used in this part:

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.''

[81 FR 85973, Nov. 29, 2016]

§ 1005.3 Importation of noncomplying goods prohibited.

The importation of any electronic product for which standards have been prescribed under section 534 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk) shall be refused admission into the United States unless there is affixed to such product a certification in the form of a label or tag in conformity with section 534(h) of the act (21 U.S.C. 360kk(h)). Merchandise refused admission shall be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the product into compliance is filed and granted under §§1005.21 and 1005.22.

[69 FR 11314, Mar. 10, 2004]

Subpart B—Inspection and Testing

§ 1005.10 Notice of sampling.

When a sample of a product to be offered for importation has been requested by the Secretary, the District Director of Customs having jurisdiction over the shipment shall, upon the arrival of the shipment, procure the sample and shall give to its owner or consignee prompt notice of the delivery or of the intention to deliver such sample to the Secretary. If the notice so requires, the owner or consignee will hold the shipment of which the sample is typical and not release such shipment until he receives notice of the results of the tests of the sample from the Secretary, stating that the product is in compliance with the requirements of the Act. The District Director of

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Customs will be given the results of the tests. If the Secretary notifies the District Director of Customs that the product does not meet the requirements of the Act, the District Director of Customs shall require the exportation or destruction of the shipment in accordance with customs laws.

§ 1005.11 Payment for samples.

The Department of Health and Human Services will pay for all import samples of electronic products rendered unsalable as a result of testing, or will pay the reasonable costs of repackaging such samples for sale, if the samples are found to be in compliance with the requirements of Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968). 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 sample is found to be in violation of the Act, even though subsequently brought into compliance pursuant to terms specified in a notice of permission issued under § 1005.22.

[73 FR 34860, June 19, 2008, as amended at 85 FR 50783, Aug. 18, 2020]

Subpart C—Bonding and Compliance Procedures

§ 1005.20 Hearing.

(a) If, from an examination of the sample or otherwise, it appears that the product may be subject to a refusal of admission, the Secretary shall give the owner or consignee a written 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 unless the owner or consignee indicates his intention to bring the product into compliance. Upon timely request, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article and may be introduced orally or in writing.

(b) If the owner or consignee submits or indicates his intention to submit an application for permission to perform such action as is necessary to bring the product into compliance with the Act, such application shall include the information required by § 1005.21.

(c) If the application is not submitted at or prior to the hearing, the Secretary may allow a reasonable time for filing such application.

§ 1005.21 Application for permission to bring product into compliance.

Application for permission to perform such action as is necessary to bring the product into compliance with the Act may be filed only by the owner, consignee, or manufacturer and, in addition to any other information which the Secretary may reasonably require, shall:

(a) Contain a detailed proposal for bringing the product into compliance with the Act;

(b) Specify the time and place where such operations will be effected and the approximate time for their completion; and

(c) Identify the bond required to be filed pursuant to § 1005.23.

§ 1005.22 Granting permission to bring product into compliance.

(a) When permission contemplated by § 1005.21 is granted, the Secretary shall notify the applicant in writing, specifying:

(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 a representative of the Department of Health and Human Services;

(4) A reasonable time limit for completing the operations; and

(5) Such other conditions as he finds necessary to maintain adequate supervision and control over the product.

(b) Upon receipt of a written request for an extension of time to complete the operations necessary to bring the product into compliance, the Secretary may grant such additional time as he deems necessary.

(c) The notice of permission may be amended upon a showing of reasonable grounds thereof and the filing of an

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