

§ 12.90

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with paragraph (e)(2) of this section, and which are not exported under Customs supervision within 90 days from the date of notice of refusal of admission or date of redelivery, shall be disposed of under Customs laws and regulations. However, no such disposition shall result in an introduction into the United States of a product in violation of the Federal Boat Safety Act of 1971 (46 U.S.C. 1451-1489).

[T.D. 76-166, 41 FR 23398, June 10, 1976, as amended by T.D. 82-220, 47 FR 52138, Nov. 19, 1982; T.D. 84-213, 49 FR 41168, Oct. 19, 1984; T.D. 86-203, 51 FR 42997, Nov. 28, 1986]

ELECTRONIC PRODUCTS

§ 12.90 Definitions.

As used in §§ 12.90 and 12.91, the term “the Act” shall mean the Public Health Service Act (42 U.S.C. 201 *et seq.*), as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b *et seq.*), and as further amended from time to time.

[T.D. 83-235, 48 FR 52436, Nov. 18, 1983]

§ 12.91 Electronic products offered for importation under the Act.

(a) *Standards prescribed by the Department of Health and Human Services.* Electronic products offered for importation into the customs territory of the United States are subject to standards prescribed under section 358 of the Act (42 U.S.C. 263f) unless intended solely for export. Prescribed standards shall not apply to any electronic product intended solely for export if:

(1) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that it is intended for export, and

(2) Such product meets all the applicable requirements of the country to which it is intended for export.

(See 21 CFR, chapter I, subchapter J.)

(b) *Requirements for entry and release.* Electronic products subject to standards in effect under section 358 of the Act (42 U.S.C. 263f), when offered for importation into the customs territory of the United States, shall be refused entry unless there is filed with the entry, in duplicate, a declaration (FDA Form FD 2877) verified by the importer

of record which identifies the products and affirms:

(1) That the electronic products were manufactured before the date of any applicable electronic product performance standard (the date of manufacture shall be specified); or

(2) That the electronic products comply with all standards in effect under section 358 of the Act (42 U.S.C. 263f), and chapter I, subchapter J, title 21, Code of Federal Regulations (21 CFR, chapter I, subchapter J), and that the certification required by section 360 of the Act (42 U.S.C. 263h) in the form of a label or tag is attached to the product; or

(3)(i) That the electronic products do not comply with all standards in effect under section 358 of the Act (42 U.S.C. 263f), and chapter I, subchapter J, title 21, Code of Federal Regulations (21 CFR, chapter I, subchapter J), but are being imported for the purpose of research, investigations, studied, demonstrations, or training, (ii) that the products will not be introduced into commerce and when the use for which they were imported is completed they will be destroyed or exported under Customs supervision, and (iii) that an exemption for these products has been or will be requested from the National Center for Devices and Radiological Health, Food and Drug Administration, in accordance with section 360B(b) of the Act (42 U.S.C. 263j); or

(4) That the electronic products do not comply with all standards in effect under section 358 of the Act (42 U.S.C. 263f) and chapter I, subchapter J, Code of Federal Regulations (21 CFR, chapter I, subchapter J), but that a timely and adequate petition for permission to bring the products into compliance with applicable standards has been or will be filed with the Secretary of Health and Human Services in accordance with section 360 of the Public Health Service Act, as amended, and as implemented by 21 CFR 1005.21.

(c) *Notice of sampling.* When a sampling of a product offered for importation has been requested by the Secretary of Health and Human Services, as provided for in 21 CFR 1005.10, the port director having jurisdiction over the shipment from which the sample is