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 procured shall give to its owner or importer of record prompt notice of delivery of, or intention to deliver, the sample. If the notice so requires, the owner or importer of record shall hold the shipment of which the sample is typical and not release the shipment until notice of the results of the tests of the sample from the Secretary of Health and Human Services stating the product fulfills the requirements of the Act.

(d) *Release under bond.* If a declaration filed in accordance with paragraph (b) of this section states that the entry

is being made under circumstances described in paragraph (b)(4) of this section, the entry shall be accepted only if the owner or importer of record gives a bond on Customs Form 301, containing the bond conditions set forth in § 113.62 of this chapter, for the production of a notification from the Secretary of Health and Human Services or his designee, in accordance with 21 CFR 1005.23, that the electronic product described in the declaration filed by the importer of record is in compliance with the applicable standards. The bond shall be in an amount deemed appropriate by the port director. Within 180 days after the entry of such additional period as the port director may allow for good cause shown, the importer of record shall take any action necessary to insure delivery to the port director of the notification described in this paragraph. If the notification is not delivered to the director of the port of entry of the electronic products within 180 days of the date of entry or such additional period as may be allowed by the port director, for good cause shown, the importer of record shall deliver or cause to be delivered to the port director those electronic products which were released. In the event that any electronic products are not redelivered to Customs custody or exported under Customs supervision within the period allowed by the port director in the Notice of Redelivery (Customs Form 4647), liquidated damages shall be assessed in the full amount of a bond if it is a single entry bond, or if a continuous bond is used, the amount that would have been taken under a single entry bond.

(e) *Release without bond—special exemptions.* For certain electronic products the Director, National Center for Devices and Radiological Health, has granted special exemptions from the otherwise applicable standards under the Act. Such exempted products may be imported and released without bond if they meet all the criteria of the special exemption. If a special exemption is granted after the product has been imported under bond in accordance with paragraph (d) of this section, the bond conditions pertaining to the notification of compliance from the Secretary of Health and Human Services shall be deemed to have been satisfied.

(f) *Merchandise refused entry.* If electronic products are denied entry under any provision of this section, the port director shall refuse to release the merchandise for entry into the United States.

(g) *Disposition of merchandise refused entry into the United States; redelivered merchandise.* Electronic products which are denied entry under paragraph (b) of this section, or which are redelivered in accordance with paragraph (d) 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 an electronic product in violation of the Act (42 U.S.C. 263f, 263h).

[T.D. 83–235, 48 FR 52436, Nov. 18, 1983, as amended by T.D. 84–213, 49 FR 41168, Oct. 19, 1984]

SWITCHBLADE KNIVES

§ 12.95 Definitions.

Terms as used in §§ 12.96 through 12.103 of this part are defined as follows:

(a) *Switchblade knife.* ''Switchblade knife'' means any imported knife, or components thereof, or any class of imported knife, including ''switchblade'', ''Balisong'', ''butterfly'', ''gravity'' or ''ballistic'' knives, which has one or more of the following characteristics or identities:

(1) A blade which opens automatically by hand pressure applied to a button or device in the handle of the knife, or any knife with a blade which opens automatically by operation of inertia, gravity, or both;

(2) Knives which, by insignificant preliminary preparation, as described in paragraph (b) of this section, can be altered or converted so as to open automatically by hand pressure applied to a button or device in the handle of the knife or by operation of inertia, gravity, or both;

(3) Unassembled knife kits or knife handles without blades which, when fully assembled with added blades,