

May 28, 1981

TO: All Foreign Manufacturers and Importers of Electronic Products for Which Applicable FDA Performance Standards Exist

FDA district offices handle the day-to-day responsibilities for control of the importation of electronic products to which FDA radiation performance standards apply. Before these products can be permitted to enter the U.S., manufacturers and importers are required to submit with each shipment certain required entry papers through the District Director, U.S. Customs Service to the appropriate FDA district office. This letter provides importers with guidance on their responsibilities, including the requesting of exemptions from certification and the submitting of petitions to bring products into compliance. All required information must be satisfactorily submitted before these products can be permitted to enter the U.S.

Enclosures

We are enclosing a copy of the following items:

1. The Radiation Control for Health and Safety Act of 1968. Your special attention is called to the provisions of Section 360 entitled "Imports".

2. A compilation of the FDA regulations published pursuant to the Act. Note particularly the provisions of 21 CFR 1005 entitled "Importation of Electronic Products".

3. HEW Publication (FDA) 77-8008 a brochure titled "Imports Radiation - Producing Electronic Products" which contains a list of FDA district offices. The import officers of these districts should be contacted by importers and import brokers regarding local procedures for importation of electronic products at the specific ports of entry within their jurisdiction. All communications relating to specific shipments of electronic products including details on the completion and submission of FDA forms and other entry papers are to be handled directly with the local FDA office. (Additional copies of the FDA forms listed in this letter are available from the FDA district office). Where necessary the field offices will forward special cases to the Bureau for consideration.

~~4. FDA Form FD 701 entitled "Importer's Entry Notice". This form must be filled out with each shipment of your product and submitted to the local FDA office.~~

[The FDA Form FD 701 has been discontinued. Use Customs Entry Forms CF 3461 or CF 3461 ALT]

5. FDA Form 766 entitled "Application for Authorization to Relabel or to Perform Other Action". This form is to be filled out for all noncompliant products which are either to be brought into compliance, or for which an exemption will be requested by the importer. This form 766 must be submitted to the local FDA office.

6. Department of Treasury Regulations, 19 CFR 12, Sections 12.90 and 12.91.

7. U.S. Customs Service Circular, RES-2-O:D:C, XENT-1-O:D:C, dated June 5, 1974. This circular presents guidelines to be used in processing importations subject to the Radiation Control for Health and Safety Act of 1968.

8. FDA Form 2877 entitled "Declaration for Products Subject to Radiation Control Standards". This form must be completed and submitted to the U.S. Customs Service when you import products for which performance standards are in effect. The Form FD 2877 provides information necessary to identify the electronic product being imported, its manufacturer, the importer, the port of entry, and, most significantly, the compliance status of the products. The importer is required to describe his product in accordance with one of four possible compliance categories. He must affirm that the product:

A. Has been manufactured prior to the effective date of the standard.

<u>Product</u>	<u>Effective Date</u>
Television Receivers	January 15, 1970
Cold Cathode Gas Discharge Tubes	May 19, 1970
Microwave Ovens	October 6, 1971
Diagnostic X-ray Equipment	August 1, 1974
Cabinet X-ray (Baggage Inspection Systems)	April 25, 1974
Cabinet X-ray (all other systems)	April 10, 1975
Lasers and Laser Products	August 2, 1976
Ultrasonic Therapy Products	February 17, 1979
High Intensity Mercury Vapor Discharge Lamps	March 7, 1980
Sunlamps and Sunlamp Products	May 7, 1980

B. Complies with the performance standard and is appropriately labeled, or,

C. Does not comply with the performance standard, but is being imported only for purpose of research, investigation, studies, demonstrations, or training, or,

D. Does not comply with the performance standard, but will be brought into compliance.

Conditions for Product Entry

When Affirmation A is made the importer must supply the FDA district office with evidence, such as a notarized statement (or foreign equivalent), from the actual fabricating manufacturer that the equipment was indeed manufactured prior to the date of the appropriate standard. The product may enter the country without bond after confirmation by the FDA that the statement is correct.

When Affirmation B is made the product will be permitted to enter the country without bond, if FDA is satisfied that all reporting (21 CFR 1002), performance (21 CFR Parts 1020, 1030 and 1040), and labeling requirements (21 CFR Part 1010) have been satisfactorily met.

In cases where Affirmation C is made, the product will be detained and an application for exemption from certification under Section 360B(b) of the Radiation Control for Health and Safety Act must be submitted to and approved by the FDA district office before the product can be permitted entry for the purpose of research, investigations, studies, demonstrations or training. It may be possible to obtain an exemption in advance of the expected date of importation. In order to apply for an exemption the importer must complete and submit forms FD 766 and 2877 along with other information, to the District Director of the FDA district responsible for the port where the product will enter. The Form FD 766 and appended information should fully describe the product or component being imported, the purpose for which it is being imported, the specific purpose (e.g., research, studies, demonstration), where it will be located, the time period the importer intends to keep it in this country and the name of the individual responsible for the control of the product. If the exemption has not been obtained prior to the time of importation,

a request for such an exemption must be made at the time of entry. When the exemption has been granted by the FDA district office, the uncertified or noncompliant product will be permitted to enter the country under a U.S. Customs Service Temporary Import Bond. These products shall then be used only in accordance with the conditions stated in the approved FD 766. No exempt products may be introduced in commerce. Uncertified or noncompliant medical or dental device for which there is an applicable performance standard (e.g., diagnostic x-ray, medical laser, etc.) may not normally be used on human subjects and may never be so used without written authorization of the Director, Bureau of Radiological Health.

In cases where Affirmation D has been made, the product will be detained and the importer must submit to the FDA district office, a petition to bring the product into compliance. This petition shall state that the importer intends to: (1) bring the product into compliance with the performance standard in accordance with a corrective action plan approved by the BRH and/or (2) fulfill certification requirements by submitting an initial report or a model change report and by affixing a certification label. This petition is to be submitted on, or as an attachment to, a Form FD 766. The proposed corrective action plan of the importer must be submitted through the district to the BRH within 10 days. If this petition is approved, the importer must, within 180 days of the conditional release of his product from Customs custody, either bring his product into compliance with the performance standard, export it from the United States, or destroy it..

Importers may also bring electronic products into compliance with the standard under Affirmation D based on the results of research, demonstration, investigation, etc. conducted under an exemption received in accordance with Section 360B(b) of the Radiation Control for Health and Safety Act. To choose this option under Affirmation D, the importer must check Affirmation D on the FD 2877 Declaration and apply for an exemption under Section 360B(b) of the Act. This exemption request shall include that information required above for products being imported under Affirmation C plus all of the requirements for an exemption under Affirmation D.

As in the case under Affirmation C, no imported electronic product that is a noncompliant medical or dental device for which there is an applicable performance standard may normally be used

on human subjects until it is brought into compliance with the performance standard and may never be so used without written authorization of the Director, Bureau of Radiological Health.

All Affirmation D entries shall be U.S. Customs Service consumption entries.

X-ray Product Identification

In order to insure accurate and expeditious processing of all import declarations and to process the entry of x-ray products with a minimum of delay, the importer must employ uniform nomenclature in identifying various x-ray systems and components. It is therefore requested that manufacturers and/or importers identify their products in accordance with the categories listed in 21 CFR 1020.30(a)(1). These categories are as follows:

1. Diagnostic x-ray systems
2. Tube housing assemblies
3. X-ray controls
4. X-ray high voltage generators
5. Tables
6. Cradles
7. Film changers
8. Cassette holders
9. Beam-limiting devices
10. Spot-film devices
11. Image intensifiers
12. Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978
13. Cephalometric devices manufactured after February 25, 1978

The above categories will need to be included on the FD 2877 Declaration in addition to a more general description of the product, (i.e., diagnostic x-ray component or diagnostic x-ray subsystem).

Completion of Import Forms

Failure to complete the importation forms and declarations satisfactorily, or failure to describe the electronic product imported, may result in the rejection of the import papers or the detention of the shipment at the port of entry until the

necessary information has been submitted and has been found to be satisfactory by the FDA district office.

You should be aware that additional requirements may apply to manufacturers and importers of medical devices, pertaining to manufacturer or distributor registration, product testing and submission of premarket notification. More detailed information may be obtained from the FDA local district office.

If you have any questions about these requirements, please do not hesitate to contact the FDA District Import Officer.

Sincerely yours, .



Walter E. Gundaker
Acting Director
Division of Compliance
Bureau of Radiological Health

Figure 10

ENTRY AND IMMEDIATE DELIVERY
(CF 3461)

TABS: ▼

DEPARTMENT OF THE TREASURY
UNITED STATES CUSTOMS SERVICE

Form Approved
OMB No. 1515-0069

ENTRY/IMMEDIATE DELIVERY

19 CFR 142.3, 142.16, 142.22, 142.24

1. ARRIVAL DATE		2. ELECTED ENTRY DATE		3. ENTRY TYPE CODE/NAME		4. ENTRY NUMBER	
5. PORT		6. SINGLE TRANS. BOND		7. BROKER/IMPORTER FILE NUMBER			
		8. CONSIGNEE NUMBER		9. IMPORTER NUMBER			
10. ULT. VATE CONSIGNEE NAME				11. IMPORTER OF RECORD NAME			
12. CARRIER CODE		13. VOYAGE/FLIGHT/TRIP		14. LOCATION OF GOODS-CODE(S) & NAME(S)			
15. VESSEL CODE/NAME							
16. U.S. PORT OF UNLADING		17. MANIFEST NUMBER		18. G. O. NUMBER		19. TOTAL VALUE	
20. DESCRIPTION OF MERCHANDISE							
21. HTS AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. TSUSA NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.		
27. CERTIFICATION				28. CUSTOMS USE ONLY			
I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met. SIGNATURE OF APPLICANT X PHONE NO. _____ DATE _____				<input type="checkbox"/> OTHER AGENCY ACTION REQUIRED, NAMELY:			
29. BROKER OR OTHER GOVT. AGENCY USE				<input type="checkbox"/> CUSTOMS EXAMINATION REQUIRED.			
				<input type="checkbox"/> ENTRY REJECTED, BECAUSE:			
DELIVERY AUTHORIZED:		SIGNATURE		DATE			

Paperwork Reduction Act Notice: This information is needed to determine the admissibility of imports into the United States and to provide the necessary information for the examination of the cargo and to establish the liability for payment of duties and taxes. Your response is necessary.

Customs Form 3461 (112085)

Figure 11

ENTRY AND IMMEDIATE DELIVERY (ALTERNATE)
(CF 3461 ALT)

ENTRY/IMMEDIATE DELIVERY 19 CFR 142.3, 142.10, 142.22, 142.24		DEPARTMENT OF THE TREASURY UNITED STATES CUSTOMS SERVICE		Form Approved OMB No. 1518-0046
 C00-0000422-3		 C00-0000422-3		Customs Form 3461ALT (061086)
1. ULTIMATE CONSIGNEE NO.	2. IMPORTER NO.	1. ULTIMATE CONSIGNEE NO.	2. IMPORTER NO.	
3. TSUSAISI		4. STATION	5. NO. OF PKGS.	
6. CTRY. ORIG.	7. MANUFACTURER ID	<input checked="" type="checkbox"/> I hereby make application for entry/immediate delivery. I certify that the information provided is accurate, the bond is sufficient, valid, and current and that all requirements of 19 CFR Part 142 have been met. SIGNATURE OF APPLICANT DATE		
8. NO. INV. PGS.	9. TOTAL INVOICE VALUE			

APPLICATION FOR AUTHORIZATION TO RELABEL OR TO PERFORM OTHER ACTION OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT AND OTHER RELATED ACTS

Form Approved; OMB No. 0910-0025. Expiration Date: November 30, 1991

Public reporting burden for this collection of information is estimated to average .25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS Hubert H. Humphrey Building, Room 721-B 200 Independence Avenue, S.W. Washington, DC 20201 Attn: PRA

and to:

Office of Management and Budget Paperwork Reduction Project (0910-0025) Washington, DC 20503

Date _____ Sample No. _____

To DIRECTOR, _____ District, Food and Drug Administration.

Application is hereby made for authorization to bring the merchandise below into compliance with the Act.

Product _____ Entry No. and Date _____

Carrier _____ Amount and Marks _____

Redelivery bond has been posted by the applicant. The merchandise will be kept apart from all other merchandise and will be available for inspection at all reasonable times. The operations, if authorized, will be carried out at _____ and will require about _____ days to complete. A detailed description of the method by which the merchandise will be brought into compliance is given in the space below:

We will pay all supervisory costs in accordance with current regulations.

Firm Name and Address _____

Applicant's signature _____

ACTION ON APPLICATION

To: _____ Date _____ (Name and Address)

Your application has been { denied because / approved with the following conditions

Time limit within which to complete authorized operations _____

When the authorized operations are completed, fill in the importer's certificate on the reverse side and return this notice to this office.

Director, _____ District

IMPORTER'S CERTIFICATE

Place _____, _____, 19____

I certify that the work to be performed under the authorization has been completed and the goods are now ready for inspection at _____

The rejected portion is ready for destruction under Customs' supervision and is held at _____

_____, Applicant

REPORT OF INVESTIGATOR / INSPECTOR

_____, 19____

TO THE PORT DIRECTOR OR DISTRICT DIRECTOR:

I have examined the within-described goods and find them to be the identical goods described herein, and that they have been _____ on _____, 19____ as authorized except _____

DATA ON CLEANED GOODS:

Good Portion _____
Rejections _____
Loss (if any) _____
Did importer clean entire shipment? _____
Time and cost of supervision _____

Inspecting Officer

DIRECTOR OF DISTRICT.

Disposed of as noted above.

Director of Customs

not redelivered within 5 days following the date required by paragraph (e)(2) of this section, liquidated damages shall be assessed in the full amount of the 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.

(f) *Products refused entry.* If a product is denied entry under the provisions of this section, the port director shall refuse to release the product for entry into the United States and shall issue a notice of the refusal to the importer or consignee.

(g) *Disposition of products refused entry into the United States; redelivered products.* Products which are denied entry under paragraph (b) of this section, or which are redelivered in accordance 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 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, springs, or other parts, are knives which 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; or

(4) Knives with a detachable blade that is propelled by a spring-operated mechanism, and components thereof.

(b) *Insignificant preliminary preparation*. "Insignificant preliminary preparation" means preparation with the use of ordinarily available tools, instruments, devices, and materials by one having no special manual training or skill for the purpose of modifying blade heels, relieving binding parts, altering spring restraints, or making similar minor alterations which can be accomplished in a relatively short period of time.

(c) *Utilitarian use*. "Utilitarian use" includes but is not necessarily limited to use:

(1) For a customary household purpose;

(2) For usual personal convenience, including grooming;

(3) In the practice of a profession, trade, or commercial or employment activity;

(4) In the performance of a craft or hobby;

(5) In the course of such outdoor pursuits as hunting and fishing; and

(6) In scouting activities.

[T.D. 71-243, 36 FR 18859, Sept. 23, 1971, as amended by T.D. 90-50, 55 FR 28192, July 10, 1990]

§ 12.96 Imports unrestricted under the Act.

(a) *Common and special purpose knives*. Imported knives with a blade style designed for a primary utilitarian use, as defined in §12.95(c), shall be admitted to unrestricted entry provided that in condition as entered the imported knife is not a switchblade knife as defined in §12.95(a)(1). Among admissible common and special purpose knives are jackknives and similar standard pocketknives, special purpose knives, scout knives, and other knives equipped with one or more blades of such single edge nonweapon styles as clip, skinner, pruner, sheep foot, spey, coping, razor, pen, and cuticle.

(b) *Weapons with fixed blades*. Importations of certain articles having a fixed unexposed or exposed blade are not within the prohibition of 15 U.S.C. 1241 through 1245. However, upon release by Customs, possession of these admissible articles which include such weapons as sword canes, camel whips, swords, sheath knives, machetes and similar devices that may be capable of use as weapons may be in violation of State or municipal laws.

[T.D. 71-243, 36 FR 18860, Sept. 23, 1971, as amended by T.D. 90-50, 55 FR 28192, July 10, 1990]

§ 12.97 Importations contrary to law.

Importations of switchblade knives, except as permitted by 15 U.S.C. 1244, are importations contrary to law and



DEPARTMENT OF THE TREASURY
U.S. CUSTOMS SERVICE
WASHINGTON



CIRCULAR: RES-2-0:D:C
xENT-1-0:D:C
DATE: JUN 5 1974

Subject: Importations of electronic products subject to radiation emission standards established by the Department of Health, Education, and Welfare

Reference: Radiation Control for Health and Safety Act of 1968; 42 U.S.C. 263b et. seq.; Subchapter J, Parts 1000-1030; 21 CFR, Chapter 1, formerly 21 CFR 278 and 42 CFR, Part 78, Subpart G; 19 CFR 12.90 and 12.91; Customs Service Circulars ENT-1-R:E:R dated March 2, 1973; ENT-1-AC dated July 25, 1972, April 11, 1972, and October 15, 1970.

1. PURPOSE

- a. To implement procedural changes and increase the enforcement of the Radiation Control for Health and Safety Act of 1968.
- b. To advise Customs officers of the recodification of Health, Education, and Welfare regulations.
- c. To consolidate, update, and supersede previous instructions.

2. BACKGROUND

- a. The Bureau of Radiological Health of the Food and Drug Administration has requested the assistance of the U. S. Customs Service in effecting a greater degree of enforcement of the above referenced "Act." As a result, a Memorandum of Understanding between the two agencies was concluded on March 20, 1974.
- b. Food and Drug will be taking a more active role in screening declarations, sampling, and making determinations at the local level. While Customs responsibilities will remain unchanged, certain procedural changes will be required. Simultaneous instructions in the form of an FDA Compliance Program Guidance Manual have been prepared by Food and Drug and are being issued to local Food and Drug offices.

c. For the information and guidance of Customs officers, the Food and Drug Administration is in the process of recodifying regulations. Health, Education, and Welfare regulations, applicable to the above noted "Act," were recodified as (21 CFR, Chapter 1, Subchapter J, Parts 1000-1030), and published in Federal Register Volume 38, Number 198, Part III, dated October 15, 1973.

3. ACTION

Effective upon receipt of this circular, the following guidelines shall be utilized in processing importations subject to the Radiation Control for Health and Safety Act of 1968.

a. The regulatory requirements involving importations subject to the "Act" are set forth in 19 CFR 12.90 and 12.91. No changes are immediately contemplated to these regulations.

b. As of this date, performance standards have been established for the following products and necessitate the submission of the required declaration with I.D. and entry:

1. Television receivers
2. Cold cathode gas discharge tubes
3. Microwave ovens
4. Cabinet and diagnostic X-ray apparatus (effective August 1, 1974)

c. District Directors shall ensure that all importations subject to the "Act" are brought to the attention of the local Food and Drug office.

d. With the exception of the use of the declaration, the same local procedures (notification, inspection, sampling, release, etc.) which apply to other imported products subject to Food and Drug inspection, should be utilized in processing importations subject to the "Act."

e. Customs will discontinue transmitting the copy of the required declaration to the Bureau of Radiological Health at Rockville, Maryland. It is to be furnished or transmitted to the local Food and Drug office.

f. District Directors shall establish procedures to ensure that the local Food and Drug office receives the duplicate copy of the declaration; either by accompanying any import documents submitted to Food and Drug and to be returned to Customs for normal processing of the importation, or as a direct mailing where local Food and Drug offices are not readily available. The original shall continue to be a part of the entry package.

g. As with other Food and Drug importations, Customs and the importer/broker are to be notified by Food and Drug of any action necessitated on each importation subject to the "Act." This does not preclude any statutory or regulatory Customs processing of the importation.

h. Any questions regarding importations subject to the "Act" should now be directed to the local or jurisdictional Food and Drug office. Operational matters requiring Headquarters assistance should be directed to the Compliance Branch, Duty Assessment Division, Office of Operations, FTS (202) 964-8651.

i. A sample declaration format reflecting appropriate changes is attached.

4. SUPERSEDED MATERIAL

a. Headquarters Circular ENT-1-R:E:R dated March 2, 1973.

b. Headquarters Circular ENT-1-AC dated April 11, 1972.

c. Headquarters Circular ENT-1-AC dated October 15, 1970.

File: RES-2-0:D:C F

R. N. Manna
ACTING Assistant Commissioner (Operations)

Attachment

Distribution: A, B, C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
DECLARATION FOR PRODUCTS SUBJECT TO
RADIATION CONTROL STANDARDS

Form Approved OMB No 0910-0025
 Expiration Date: June 30, 1994.

- INSTRUCTIONS**
 1 Type or print with ball point pen.
 2 Submit one copy with U.S. Customs Service Entry Papers.
 3 Attach two copies to Form FDA 701, "Importer Entry Notice."

DISTRICT/PORT DIRECTOR OF CUSTOMS

PORT OF ENTRY	ENTRY NO.	DATE
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PRODUCT IDENTIFICATION

NAME AND ADDRESS OF MANUFACTURER

NAME AND ADDRESS OF IMPORTER OF RECORD

ULTIMATE CONSIGNEE (If not Importer of Record)

QUANTITY	TYPE	BRAND NAME	MODEL NO.
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FOR X-RAY, LIST APPROPRIATE SYSTEM OR COMPONENT CATEGORY

AFFIRMATION (Check appropriate statement and sign)

I/We hereby declare.

- A.** That the electronic products identified above were manufactured prior to the date of any applicable electronic product performance standard
- Date of Manufacture _____
- B.** That the electronic products identified above comply with the performance standards prescribed in Food and Drug Administration Rules 21 CFR 1010 which are applicable at date of manufacture and that a certificate in the form of a tag or label to this effect is affixed to each product
- C.** That the electronic products identified above do not comply with the performance standards prescribed in Food and Drug Administration Rules 21 CFR 1010 but are being imported for the purpose of research, investigations, studies, demonstrations, or training. An exemption for these products has been or will be requested of the Director of the FDA Center for Devices and Radiological Health in accordance with Section 538 (21 U.S.C. 360oo) of the Radiation Control for Health and Safety Act. They will not be introduced into commerce, and when their mission is completed they will be destroyed or exported under the United States Customs Service supervision
- D.** That the electronic products identified above do not comply with the performance standards prescribed in Food and Drug Administration Rules 21 CFR 1010 but that a timely and adequate petition for permission to bring the product into compliance with the applicable standard has been or will be filed with the Food and Drug Administration in accordance with 21 CFR 1005.21. These products will remain under bond and not be introduced into commerce until notification is received from the Food and Drug Administration, that the products are in compliance with applicable standards

¹ Signature of Importer of Record _____

¹ Facsimile of signature not acceptable

Public reporting burden for this collection of information is estimated to average 16 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Reports Clearance Officer, PHS
 Hubert H. Humphrey Building, Room 721-B
 200 Independence Avenue S.W.
 Washington, DC 20201
 Attn: PRA

and to: Office of Management and Budget
 Paperwork Reduction Project (0910-0025)
 Washington, DC 20503

Please DO NOT RETURN this form to either of these addresses.

INSTRUCTIONS TO IMPORTERS/BROKERS OF ELECTRONIC PRODUCTS

The following information is provided to assist in completing the FDA 2877 Declaration.

In those cases where Affirmation C is made on Form FDA 2877 stating that the product(s) does not comply with the applicable performance standard, the product(s) may only be imported for purposes of research, investigations, studies, demonstrations, or training (See CP Circular, 7382.007A regarding certain shipments of television receivers, microwave ovens and certain Class I laser products). The product(s) will then be detained by the District Food and Drug Administration Office, and before the product(s) is allowed to be used for its intended purpose (research, investigations, studies, demonstrations or training) an exemption from certification must be submitted to the District Office for approval. Such requests must include the following:

1. A full description for the subject electronic product(s).
2. The purpose for which the product(s) is being imported.
3. How the product(s) will be used.
4. Where the product(s) will be located.
5. The approximate length of time the product(s) will be in this country.

The request for exemption from certification may be made on the FDA 766 form or it may be presented as an attachment to the Form FDA 766. Since products for which "C" Affirmations are made will be under a Temporary Import Bond, ultimate disposition is limited to export or destruction under U.S. Customs supervision when the purpose has been achieved or the time limit of the exemption has expired.

In those cases where Affirmation D is made on Form FDA 2877 stating that the product(s) does not comply with the applicable performance standard but will be brought into compliance, a statement as to how the product will be brought into compliance is required. (Affirmation D is also made for failure to provide reports, failure to certify, etc.) The product(s) will be detained by the District Office; and the importer/broker must file a statement with the FDA 766, or as an attachment to it, indicating the procedure intended to bring the product into compliance. This documentation must be submitted to the District Office for approval before permission will be granted to modify the product as described in the application.

The Form FDA 766 must include a statement that the product will be brought into compliance by the submission of a satisfactory corrective action plan and/or an initial or model change report. The FDA Form 766 must also include:

1. A full description of the electronic product(s).
2. The purpose for which the product(s) is being imported.
3. How the product(s) will be used.
4. Where the product(s) will be located.
5. The approximate length of time necessary to bring the product(s) into compliance.

If an importer/broker of diagnostic x-ray equipment intends to import uncertified x-ray equipment into the United States for purposes of research, investigation, studies, demonstrations, or training but also wishes to retain the option of bringing the product into compliance with the performance standard, check Affirmations C and D on the FDA 2877 and insert the word "or" between the Affirmations. Note: The U.S. Customs Service will treat this entry as a "D" Affirmation for purposes of duty.

This option is only available for uncertified diagnostic equipment manufactured after August 1, 1974. Such requests must include the following:

1. A full description of the subject electronic product(s).
2. A statement of the need to use the option "C" or "D" Affirmation.
3. A description of how the product(s) will be used under Affirmation C.
4. A statement of how the product(s) will be brought into compliance under Affirmation D.
5. Where the product(s) will be located.
6. The approximate length of time necessary to evaluate or demonstrate the product(s) and the time necessary to bring the product(s) into compliance (both actions must be accomplished within the period of time granted by FDA).

Ultimately, the product(s) must be brought into compliance with the applicable standard in accordance with a corrective action plan which has been approved by the FDA or the submission of an initial or model change report which assures that the product is in compliance with the performance standard. If the product(s) are not brought into compliance within the allotted time frame of the approved application and an extension is not requested of, or granted by the FDA, the District Office shall refuse entry on the shipment and require the product(s) to be either exported or destroyed under U.S. Customs supervision.