

CPG Sec. 394.500 Importation of Television Products, Microwave Ovens, and Inherent Class I Laser Products for Investigation and Evaluation during Design Development

Document Effective Date: July 29, 2004

This document supersedes Compliance Policy Guide (CPG) "Sec. 394.500 Importation of Television Receivers and Microwave Ovens for Investigation and Evaluation (CPG 7133.22)" that was issued on March 1, 1984.

U.S. Department of Health and Human Services Food and Drug Administration Office of Regulatory Affairs

Preface

Public Comment:

At any time, interested persons may submit written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The comments are to be identified with the title of this guidance document. Such comments will be considered when determining whether to amend the current guidance. []

Additional Copies:

A copy of the guidance may be downloaded to a personal computer with access to the Internet. The guidance may be accessed at http://www.fda.gov/ora/compliance_ref/cpg/cpgdev/cpg394-500.html

From 1996 CPG Manual

Sec. 394.500 Importation of Television Receivers and Microwave Ovens for Investigation and Evaluation (CPG 7133.22)

BACKGROUND:

Federal regulations require that all imported electronic products for which applicable FDA radiation performance standards exist, shall comply with these standards and shall bear certification of such compliance. Before these products can be permitted to enter the U.S., manufacturers and importers are required to submit with each shipment certain required import entry papers through the District Director, U.S. Customs Service to the appropriate FDA district office. Currently, imported television receivers and microwave ovens must meet the requirements of performance standards (21 CFR 1020.10 and 21 CFR 1030.10 respectively), or be detained.

Section 360B(b) of the Radiation Control for Health and Safety Act of 1968 provides for possible exemption from certification of electronic products for the purpose of research, investigations, studies, demonstrations, or training. Current FDA policy is that exemptions for any electronic products may be granted for a period of 180 days when imported for these purposes. During this time, the products remain in import detention status and are allowed in the country by means of written declaration (form FD 2877 "Affirmation C") filed with the FDA and through a Temporary Import Bond (TIB) filed with Customs. Liquidation of the Customs bond for these products, is attained only through their exportation or destruction.

POLICY:

It is the opinion of the FDA that these procedures are unnecessarily restrictive for most Affirmation C type television and microwave oven entries. These shipments are usually of small quantity and are tested and evaluated under controlled conditions by technically trained individuals. These products pose no public health hazard as long as they are limited in number and kept out of commercial distribution. Therefore, under the authority of section 360B(b) of the Radiation Control for Health and Safety Act, television or microwave oven products imported for the purpose of research, investigations, studies, demonstrations, or training are hereby exempt from their respective performance standard provided the following conditions are strictly adhered to, by the manufacturer/importer:

1. Each shipment consists of 10 or fewer units.
2. Each receiver and its shipping carton bears a label which states "TESTING/EVALUATION RECEIVER (OR OVEN) - NOT TO BE SOLD IN THE UNITED STATES. THIS TELEVISION RECEIVER (MICROWAVE OVEN) HAS NOT

BEEN TESTED FOR COMPLIANCE WITH THE U.S. FEDERAL PERFORMANCE STANDARD FOR TELEVISION RECEIVERS (MICROWAVE OVENS)".

3. Form FD 701, Importers Entry Notice is filed with the FDA and attests that the receivers or ovens are intended for research, investigation, studies, demonstration or testing, as the case may be, and that the receivers or ovens will not be commercially distributed.

Movement in commerce of uncertified television receivers or microwave ovens imported under this exemption is a violation of Section 360B(a)(1) of the Act and violators shall be subject to civil penalties of \$1,000 per violation up to a maximum of \$300,000.

Issued: 3/1/84

From 2000 CPG Manual

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(CPG 7133.22)

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