Compliance Policy Guide
Sec. 390.200 Determination by Secretary that Product Fails to Comply or has Defect - 21 CFR 1003.11

Guidance for FDA Staff

This document supersedes Sec. 390.200 Determination by Secretary that Product Fails to Comply or has Defect – 21 CFR 1003.11, previously revised on 03/1995.

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I. Introduction:

This document is intended for FDA staff, regulated manufacturers, and the general public. This document clarifies the scope of a manufacturer's responsibility for the radiation safety of their electronic products.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background:

Section 535(e) of the Federal Food, Drug, and Cosmetic Act, (Act) Subchapter C-Electronic Product Radiation Control (P.L. 90-602), and 1003.11 of the implementing regulations (21 CFR 1003.11) state that if the Food and Drug Administration determines that any electronic product either does not comply with an applicable Federal performance standard, or has a defect that relates to the safety or use of such product, the manufacturer shall immediately be notified in writing of the alleged defect or noncompliance, the findings of the FDA, and all information on which the findings are based. The notification shall also state a reasonable period of time during which the manufacturer may present his view and evidence to establish that

there is no failure of compliance, or that the alleged defect does not exist. If the FDA alleges a defect or failure to comply which the manufacturer believes was caused by the user rather than through any fault in design, production, or assembly, the manufacturer will have an opportunity to present evidence in substantiation of his position.

III Policy:

A manufacturer of electronic products is responsible for all defects or failures to comply which are the result of design, production, or assembly. However, if it can be shown that a product no longer meets the requirements of a performance standard because of modification of the equipment by unauthorized personnel, installation of improper replacement parts or materials, or unforeseeable abuse of the equipment by the owner or user, there may be a basis for a finding that certain of the notification requirements and the repair, replace and refund provisions (21 CFR 1003 and 1004) will not apply.

The manufacturer bears the burden of proof in establishing that a defect or *failure to comply is due to a cause other than faulty design, production, or assembly.* The FDA's mandate to protect the public health and safety under P.L. 90-602, together with the Act's specification that measures to enforce the control of electronic product radiation be directed against the manufacturer of a product, requires that the primary responsibility of a manufacturer for the safety of his product not be lifted unless the responsibility can clearly be placed on another. FDA will refrain from requiring the manufacturer to repair, replace, or refund only in those situations where there is no reasonable basis for believing that a violation of the Act resulted from a manufacturer's act or omission.

For example, a certain amount of normal wear will occur in electronic products. If such normal wear results in radiation emitted by the product exceeding the limit prescribed in an applicable standard, the manufacturer may be charged with *a failure to comply* because of his failure to design the product to maintain an acceptable level of radiation emission over its useful life. The distinction between normal wear and damage resulting from misuse of the equipment is something which the manufacturer would have to justify. Similarly, a manufacturer will be held responsible when he fails to act reasonably to inform users of the equipment and service personnel of the need for, and methods of proper servicing.

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