BEFORE

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

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 noncompliance which the manufacturer believes was caused by the user rather than through any fault in manufacture, the manufacturer will have an opportunity to present evidence in substantiation of his position.

POLICY:

As a general rule, a manufacturer is responsible for defects or noncompliance. However, if it can be shown that a product no longer meets 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 noncompliance is due to a cause other than faulty manufacture. 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 noncompliance because of his failure to design the product to maintain an acceptable level of radiation leakage 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.

Material between asterisks is new or revised

Source:
http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM073911

AFTER

Electronic Product Defect / Non-Compliance Policy Section 390.200

Introduction

This topic describes FDA policy for an electronic product defect or non-compliance as determined by the Secretary.

Regulations

This policy originates from the following sources:

- Section 535(a) of the Federal Food, Drug, and Cosmetic Act
- Subchapter C – Electron Product Radiation Control (P.L. 90-602), and
- 1003.11 of the implementing regulations (21 CFR 1003.11).

Policy

The manufacturer is responsible for defects or non-compliance.

Secretary responsibility

The Secretary determines whether an electronic product

- does not comply with an applicable Federal performance standard, or
- has a defect that relates to the safety or use of the product.

Process

The table below describes the process for notification and resolution of a product defect or non-compliance.

Stage	Description
1	FDA determines that an electronic product contains a defect or is in non-compliance.
2	FDA provides the manufacturer with written notification containing a(n) • explanation of the alleged defect or non-compliance • outline of FDA findings including information on which the findings are based, and • timeframe in which the manufacturer may defend the allegation.

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Process, continued

Stage	Description
3	The manufacturer is given a reasonable period of time in which to present evidence to establish that • there is no failure of compliance • the alleged defect does not exist, or • the defect was caused by the user rather than through any fault in manufacture.
4	FDA determines whether the manufacturer is held liable for the defect or non-compliance. The FDA's decision is based on the "Defense guidelines" explained on the following page.

Burden of proof

The FDA's mandate to protect the public health and safety under P.L. 90-602 states that the manufacturer bears the burden of proof in establishing that a defect or non-compliance is due to a cause other than faulty manufacture. The manufacturer is responsible for justifying the distinction between normal wear and damage resulting from misuse of the equipment.

Defense guidelines

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 table below explains FDA guidelines for determining whether a manufacturer is held responsible for the defect or non-compliance.

Continued on next page

Electronic Product Defect / Non-Compliance Policy
Section 390.200, Continued

Defense guidelines, continued

If the manufacturer ...	Then the manufacturer is ...
is able to show that a product no longer meets a performance standard due to any of the following: • modification of equipment by unauthorized personnel • installation of improper replacement parts or materials, or • unforeseeable abuse of equipment by the owner or user	not held liable for the non-compliance.
• is not able to reasonably defend the non-compliance, or • failed to inform equipment users and service personnel of the need for, and methods of, proper servicing	held liable for the non-compliance.

Non-compliance 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 non-compliance because of failure to design the product to maintain an acceptable level of radiation leakage over its useful life.