CPG Sec. 390.300 Assessment of Civil Penalties Against Manufacturers and Importers of Electronic Products

BACKGROUND:

The purpose of this Compliance Policy Guide is to indicate when the Agency will recommend civil penalties.

Section 539(b)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), Subchapter C-Electronic Product Radiation Control (P. L. 90-602) states that any person who violates the prohibited acts of this law shall be subject to a civil penalty of not more than $1000. The law states that "For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by Section 538, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000." *(Note that civil penalty amounts are revised periodically to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990. In 2004, the penalties above were raised to $1,100 per violation and $330,000 maximum. Updates to civil penalty amounts will be published in 21 CFR 17.2.)*

NOTE: For this purpose the terms "manufacturers" and "importers" do not include assemblers who take components and assemble, replace, or install them in systems. For guidance on assemblers of diagnostic x-ray equipment systems refer to CPG 7133.12 (See Sec. 398.325)

POLICY:

The Agency will consider civil penalty without prior warning in those instances where there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death, or where responsible persons show intentional disregard for the law. For example:

1. Failure of a manufacturer to notify the FDA upon discovery that a product, which has left the place of manufacture, contains a defect or fails to comply with an applicable performance standard;
   or

2. Failure of a manufacturer to submit a required report in conjunction with evidence of
    a. the distribution of a product that fails to comply with a performance standard;
    or
    b. the distribution of a product that is defective and such defect poses a significant risk of injury; or
3. Issuing false certification when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading;
    or
4. Refusal to permit entry or allow inspection, or to permit access to or copying of records by duly authorized representatives as required under the FFDCA, such refusal being in response to a warrant for inspection;
    or
5. Distribution of a product that is noncompliant for the same or similar reasons found noncompliant under mandatory recall or when the noncompliance was known to the manufacturer;
    or
6. Refusal to initiate corrective action (recall) when properly notified by CDRH.

The Agency will generally not actively consider civil penalties for first time notification of violations of the FFDCA that would not result in serious adverse health consequences and where intentional disregard for the law is not documented. Civil penalties will be considered if such violations are not corrected or violations continue or recur after appropriate warning. FDA will notify responsible parties of all violation(s) through a written notification. If this notification does not result in correction of the violation(s) or similar violations continue to occur, the Agency will generally issue a Warning Letter in an effort to obtain compliance. If this effort fails, civil penalty will be considered.

Examples of violations to be considered for civil penalties after prior warning are represented by, but not limited to, the following:

1. Distribution of product that does not comply with an applicable performance standard not deemed by the Agency to be a minor violation of the performance standard.
2. Refusal to notify purchasers.
3. Failure to implement an order to notify within a reasonable time.
4. Failure to submit a required report or the submission of an incomplete or inadequate report.
5. Failure to establish and maintain records or serious deficiencies in a manufacturer's record keeping system that could result in a recall being ineffective, if one were required.
6. Failure to adequately carry out a recall because of nonexistent or inadequate manufacturer distribution records.[1]

Generally, civil penalties will not normally be considered for minor violations. The Agency considers

minor violations to be those violations of the FFDCA that present little, or no risk of injury or danger to health. Pursuant to Section 539(d) the Agency will issue written warning and/or notice to the responsible persons for minor violations and consider whatever other administrative/regulatory action best serves the public interest. Examples of minor violations include a label not permanently affixed to a product, or a manufacturer report that does not sufficiently explain a testing program.

Material between asterisks is new or revised

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[1] A recall may also be ineffective because required dealer/distributor sales records were not provided on written request by the manufacturer. If the dealer/distributor refuses to provide required sales records to the manufacturer, appropriate notice and warning will be given to obtain compliance. Civil penalties will be considered against the dealer/distributor where this effort fails.

More in Compliance Policy Guides (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm)

Foreword: Compliance Policy Guides (CPGs) (/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm)

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