Compliance Policy Guide
Sec. 390.100 Definition of "Commerce" - 21 CFR 1000.3(d)

Guidance for FDA Staff

This document supersedes Sec. 390.100 Definition of “Commerce” – 21 CFR 1000.3(d) previously revised on 03/2005.

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I. Introduction:

This document is intended for FDA staff, regulated manufacturers, and the general public. This document clarifies the legal status of an individual who manufactures an electronic product solely for his own use in his own commercial activities.

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 538(a)(1) of the Federal Food, Drug, and Cosmetic Act, Subchapter C-Electronic Product Radiation Control prohibits the introduction into commerce of any electronic product which does not conform to an applicable standard.

Questions have been raised as to whether a person who manufactures an electronic product, for which a standard has been prescribed, for use solely in his own commercial activities or manufacturing process, has introduced the product into commerce.

III Policy:

Such a person would not have introduced the product into commerce within the meaning of Section 538(a)(1). However, Section 538(a)(5) of the Act makes it a prohibited act for any person to fail to issue a certification as required by Section 534(h), regardless of whether the electronic product in question has itself been physically introduced into commerce. The assembly and use of an electronic product by a person engaged in the business of assembling that product (as defined in Section 531(2) for commercial purposes in his own facility affects interstate commerce; thus Section 534(h) would require that the manufacturer certify that the product conforms to the relevant standard. However, if that person in no way receives compensation for the assembly and use of the product, he would not be engaged in the business and therefore would not be a manufacturer subject to Section 534(h) and 538(a)(5).

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