

CPG Sec. 300.750 Class III Devices Subject to 515(b) Requirements

BACKGROUND:

Section 515(b) of the Federal Food, Drug, and Cosmetic Act (the Act) specifies that FDA will promulgate regulations requiring that the class III devices specified below have an approval of an application for premarket approval (PMA). Class III devices are described in section 513(a)(1)(C) of the Act.

The devices covered by 515(b) requirements fall into two categories:

1. Devices in commercial distribution before May 28, 1976, (preamendment devices) that were subsequently classified by the Food and Drug Administration (FDA) as class III devices by means of classification regulations promulgated under section 513 of the Act.
2. Devices offered for commercial distribution on or after May 28, 1976, (postamendment devices) that are determined through the 510(k) process to be substantially equivalent to class III preamendment devices.

After classification - in the case of category (1), or after substantial equivalence has been established by 510(k) premarket notification submissions - in the case of category (2), these devices may continue to be marketed commercially without an approved PMA until FDA publishes a final rule under 515(b) to require the filing of a PMA. The PMA may take the form of a notice of completion of a Product Development Protocol (PDP) as described in section 515(f) of the Act.

When a 515(b) final regulation is published in the Federal Register, a PMA or a notice of completion of a PDP for the device must be filed with FDA by the manufacturer, initial distributor within the United States, if the device is imported, or the exporter. The Act requires that filing be made within 90 days of the date of promulgation of that final regulation, or thirty months after the publication of the final classification of the device, whichever is later. (See 501(f)(2)(B)). Indeed, it may be several years after the final classification regulation under section 513 is published before FDA publishes the final 515(b) regulation for a class III device requiring that a PMA or PDP be filed.

Ultimately, FDA must approve the PMA or declare that the PDP has been completed, or the device becomes adulterated under section 501(f)(1)(A) of the Act.

POLICY:

For a 515(b) device, a PMA or notice of completion of a PDP must be filed by the date identified in the published section 515(b) regulation. If filing is not made, devices distributed after that date are adulterated under section 501(f)(1)(A) of the Act except for devices subject to an Investigational Device Exemption (IDE) approved under section 520(g) of the Act and devices *subject to* an exemption under 801(e)(2) of the Act.

Any 515(b) device already in commercial distribution that was introduced or delivered for introduction into commerce prior to the date identified in the published 515(b) regulation may be permitted to

remain in commerce. This does not apply if action is necessary to protect the public health or the device is determined to present an unreasonable risk of substantial harm to the public health.

REGULATORY GUIDANCE:

Prior to submitting a recommendation for direct reference seizure, the Center for Devices and Radiological Health, Office of Compliance (HFZ-300), shall be contacted to verify that a PMA or PDP has not been filed.

The following represents criteria for recommending direct reference seizure to the *Office of Medical Device and Radiological Health Operations with consult to the* Division of Enforcement, Office of Enforcement and Import Operations, Office of Operations, Office of Regulatory Affairs, Food and Drug Administration:

When class III medical devices are introduced into commerce by a manufacturer, initial distributor within the U.S. of an imported device, or exporter, (1) after the date identified in the published section 515(b) regulation without a filed PMA or PDP, or (2) an approved IDE, or (3) *are not exported* in accordance with section 801(e)(2) of the Act, the device is adulterated and subject to direct reference seizure.

SPECIMEN CHARGE:

The article is adulterated within the meaning of section 501(f)(1)(A) of the Act in that it is a class III medical device for which no application for premarket approval or notice of completion of a product development protocol has been filed in accordance with a regulation promulgated under section 515(b) of the Act, and the medical device is not exempt from the requirements of section 515 by section 520(g) * *.

Material between asterisks is new or revised

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