

of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease.

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that:

[t]he thirty month 'grace period' afforded after classification of a device into class III \* \* \* is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval (H. Rept. 94-853, 94th Cong., 2d sess. 42 (1976)).

The SMDA added section 515(i) to the act requiring FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMAs and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, the SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Indeed, proceeding directly to rulemaking under section 515(b) of the act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMAs have not been

required either be reclassified to class I or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy set forth FDA's plans for implementing the provisions of section 515(i) of the act for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups.

Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used or are in very limited use. FDA's strategy is to call for PMAs for all group 1 devices in an omnibus section 515(b) of the act rulemaking action. In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA implemented this strategy by proposing requiring the filing of a PMA or a notice of completion of a PDP for 43 class III preamendments devices. Subsequently, in the **Federal Register** of September 27, 1996 (61 FR 50704), FDA called for the filing of a PMA or a notice of completion of a PDP for 41 preamendments class III devices.

Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. In the **Federal Registers** of August 14, 1995 (60 FR 41986), and of June 13, 1997 (62 FR 32355), FDA issued an order under section 515(i) of the act requiring manufacturers to submit safety and effectiveness information on these group 2 devices so that FDA can make a determination as to whether the devices should be reclassified.

Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA intends to issue proposed rules to require the submission of PMAs for the 15 high priority devices in this group in accordance with the schedule set forth in the strategy document. In the **Federal Registers** of August 14, 1995 (60 FR 41984), and of June 13, 1997 (62 FR 32352), FDA issued an order under section 515(i) of the act for the 27 remaining group 3 devices requiring manufacturers to submit safety and effectiveness information so that FDA can make a determination as to whether the devices should be reclassified or retained in class III.

## II. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, the agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that " \* \* \* the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d) (21 CFR 812.2(d)), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days, after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the final rule to avoid interrupting investigations.