DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration [Docket No. 94N-0418]

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information

AGENCY: Food and Drug Administration, HHS.

11115.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of 27 class III devices to submit to FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requesting this information in order to determine, for each device, whether the classification of the device should be revised, or whether a regulation requiring the submission of premarket approval applications (PMA's) for the device should be promulgated. Based on preliminary information, FDA believes these 27 devices are not likely candidates for reclassification and, therefore, will likely require the submission of PMA's sometime in the future.

DATES: Summaries and citations must be submitted by the dates listed below.

ADDRESSES: Submit summaries and citations to the Documents Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ– 404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such

devices, have been classified by FDA. This notice refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as "preamendments devices."

that date, as "preamendments devices." Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a product development protocol (PDP), is not required until 90 days after FDA promulgates a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations of 21 CFR part 812 until the date stipulated by FDA in the final rule requiring the submission of a PMA for that device. If a PMA or a 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.

To date, FDA has issued final rules requiring the submission of PMA's for nine preamendment class III devices. Additionally, FDA has issued proposed rules for 10 other devices. There are 116 remaining preamendment class III devices for which FDA has not yet initiated action requiring the submission of PMA's.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101-629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to order manufacturers of preamendment class

III devices for which no final regulation has been issued requiring the submission of PMA's to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III; and, for devices remaining in class III, to establish a schedule for the promulgation of a rule requiring the submission of PMA's for the device.

In the Federal Register of May 6, 1994 (59 FR 23731), FDA announced its strategy for addressing the remaining preamendment class III devices. In that notice, FDA made available a document setting forth its strategy for implementing the provisions of the SMDA which require FDA to review the classification of certain class III devices, and either reclassify them into class I or class II or retain them in class III. Pursuant to this plan, the agency divided the universe of preamendment class III devices into the following 3 groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are very limited in use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. There are a total of 43, 31, and 42 (15 high priority), devices in Groups 1, 2, and 3 respectively.

In the May 6, 1994, notice, FDA announced its intent to call for the submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intent to issue an order under section 515(i) of the act for the remaining Group 3 devices and all of the Group 2 devices. Under section 515(i) of the act, FDA is authorized to require the submission of the adverse safety and effectiveness information identified in the summary and citation submitted in response to this order, if such information is available. Based