2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: April 15, 1996. FDA has verified the applicant's claim that the new drug application (NDA) for Flowmax™ (NDA 20–579) was initially submitted on April 15, 1996.

3. *The date the application was approved*: April 15, 1997. FDA has verified the applicant's claim that NDA 20–579 was approved on April 15, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 21, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 19, 1998, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 26, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–19379 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N–0473, 98P–0275, 98P–0215, 98P–0216, and 98P–0338]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of petitions requesting exemption from the premarket notification requirements for certain class II devices. FDA is publishing this notice in order to obtain comments on these petitions in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Written comments by August 20, 1998.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Pub. L. 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 101–629)), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination

regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the World Wide Web on the CDRH Home Page at ''http://www.fda.gov/cdrh'' or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. List of Petitions

FDA has received the following petitions requesting an exemption from premarket notification for class II devices:

1. Sandhill Scientific Inc., 21 CFR 876.1725 *Gastrointestinal motility monitoring system*.

2. Welch Allyn, Inc., 21 CFR 886.1570 *Ophthalmoscope*.

3. Computerized Medical Systems, Inc., 21 CFR 892.5840 *Radiation therapy simulation system*, exemption requested only for Radiation Oncologist Data Entry Workstation.

4. Chemicon International Inc., 21 CFR 866.3175 *Cytomegalovirus serological reagents*, and 21 CFR 866.3900 *Varicella-zoster virus serological reagents*.

IV. Comments

Interested persons may, on or before August 20, 1998, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The petitions and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 10, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–19316 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0437]

New Model Medical Device Development Process; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration FDA is announcing the availability of a document entitled ''New Model Medical Device Development Process.'' In this document, FDA outlines a new model for the investigational device exemption (IDE) and premarket approval application (PMA) development and review process. FDA is issuing this document as part of its commitment to improve the IDE and PMA development and review process.

DATES: Written comments concerning this document must be received by October 19, 1998.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Written comments concerning this document must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies on a 3.5'' diskette of ''New Model Medical Device Development Process'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

FOR FURTHER INFORMATION CONTACT: Robert R. Gatling, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1220.

SUPPLEMENTARY INFORMATION:

I. Background

Despite a marked improvement in device approval times, FDA's Center for Devices and Radiological Health (CDRH) is committed to substantial improvement of the IDE application and PMA development and review process. Often FDA's involvement with the product has been greatest at the end of the process—during review of the PMA. The lack of early and effective FDA and sponsor interaction too often results in a PMA with significant flaws requiring repair, including development of additional data, and multiple cycles of PMA review. These cycles can be costly and time consuming both for the medical device industry and FDA and can delay marketing of new devices.

As part of its reengineering process, CDRH is proposing a new model for the development and review of such class III medical devices that includes three tracks: (1) ''Expedited'' review for devices which offer significant advantages over current therapy; (2) ''standard'' review for most devices; and (3) ''streamlined'' review for devices which are very well understood by both the sponsor and FDA.

The new model also encourages interaction between the agency and the applicant, including early agreement on the overall development plan, and offers modular submission and review building the application and administrative file over time.

The guidance document outlines why FDA believes that the model will lead to ''fast, fair, and smart'' decisions that bring safe and effective devices to market as early as possible.

This guidance document represents the agency's current thinking on expediting the IDE/PMA process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations or both. FDA is issuing this as a Level 1 guidance document. Public comment prior to implementation is not required because the guidance is presenting a less burdensome policy that is consistent with the public health.

II. Electronic Access

In order to receive ''New Model Medical Device Development Process'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 1–800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1101) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer