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

with access to the Web. Updated on a regular basis, the CDRH home page includes ''New Medical Device Development Process'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 1–800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, on or before October 19, 1998, submit to the Dockets Management Branch (address above) written comments regarding this document. 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 document and received comments may be seen in the Dockets Management Branch 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. 98–19318 Filed 7–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0133]

Revised Guidance for Industry on Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance for industry entitled ''Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements.'' Section 126 of the Food and Drug Administration Modernization Act of 1997 (Modernization Act) amends the Federal Food, Drug, and Cosmetic Act (the act) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol ''Rx only'' instead of the ''Caution: Federal law prohibits dispensing without prescription'' statement. In addition, the requirement that the labels of certain habit-forming drugs bear the statement ''Warning-May be habit forming'' has been repealed. The revised guidance changes the implementation schedule provided in the original guidance dated February 1998, and answers certain questions concerning implementation of these amendments.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance for industry can be obtained on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857 or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), Food and Drug Administration, Office of Generic Drugs, 7500 Standish Pl., Rockville, MD 20855, 301–827–5846, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a revised guidance for industry entitled ''Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997— Elimination of Certain Labeling Requirements.'' Section 126 of Title I of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), signed into law by President Clinton on November 21, 1997, amends section 503(b)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353(b)(4)) to require, at a minimum, that prior to dispensing, the label of prescription products contain the symbol ''Rx only'' instead of the ''Caution: Federal law prohibits dispensing without prescription'' statement. In addition, section 502(d) of the act (21 U.S.C. 352(d)), that required the labels of certain habit-forming drugs to bear the statement ''Warning–May be habit forming'' is repealed. The amendments to section 503(b)(4) and the repeal of section 502(d) of the act became effective February 19, 1998.

FDA published a notice in the **Federal Register** of March 13, 1998, announcing the availability of the original guidance (63 FR 12473) and soliciting comments. Three comments on the guidance were submitted to the docket. In response to the comments, and to questions that were asked concerning the implementation of section 126 of the Modernization Act, FDA is issuing a revised guidance.

The revised guidance: (1) Describes the new prescription drug labeling requirements of the act as amended by the Modernization Act, (2) changes the implementation schedule previously described in the February 1998 guidance, and (3) answers certain frequently asked questions about the provision. The revised guidance advises that FDA does not intend to object if a sponsor of a currently approved product implements section 126 of the Modernization Act at the time of the next revision of its labels, or by February 19, 2003, whichever comes first, and reports these minor changes in the next annual report. For pending