FOR FURTHER INFORMATION CONTACT: Sharon A. Benz, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 19, 1980 (45 FR 62552), FDA announced that a petition (GRASP C2182) had been filed by Flett Development Co. and Rumose Products Co., Divisions of the James Flett Organization, Inc., currently at 422 North Northwest Hwy., Park Ridge, IL 60068. This petition proposed to amend the GRAS regulations to affirm that use of processed kraft paper and corrugated board as an ingredient in animal feeds is GRAS. James Flett Organization, Inc., has now withdrawn the petition without prejudice to a future filing.

Dated: September 17, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–25915 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98N–0473, 98P–0215, 98P–0216, 98P–0275, 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 an order denying four petitions requesting exemptions for five devices from the premarket notification requirements for certain class II devices. FDA is publishing this notice in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: September 29, 1998.

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. 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*.

On July 21, 1998 (63 FR 39098), FDA published a notice announcing that

these petitions had been received and providing an opportunity for interested persons to submit comments on the petitions by August 20, 1998. FDA received no comments. FDA has reviewed these petitions and, for the following reasons, has determined that these devices do not meet the criteria for exemption described previously and is, therefore, issuing this order denying the petitions to exempt these devices from the requirements of premarket notification.

1. *Gastrointestinal motility monitoring system*. Gastrointestinal motility monitoring systems could include a wide variety of devices to measure and assess the functioning of the gastrointestinal tract. The gastrointestinal monitoring systems including such components as electronic instruments, recorders, displays, and software are viewed as integral components of the system and must be evaluated together with the monitoring probes or catheters. FDA believes that review of all components of the system is necessary to provide adequate labeling and to ensure the safety and effectiveness of these products in comparison to legally marketed devices of this type.

The submission has not provided sufficient information that demonstrates that the characteristics and labeling, which are necessary to determine acceptable device performance, are well established. Further, it is neither apparent, nor has it been established, that changes in the device that could affect safety and effectiveness, and lead to device errors, would either: (a) Be readily detectable by users by visual examination or other means, such as routine testing, before causing harm; or (b) not materially increase the risk of incorrect output potentially leading to incorrect diagnosis.

2. *Ophthalmoscope*. The petition, as presented, does not meet the criteria for exemption, because changes in the device that could affect safety and effectiveness would not be readily detectable by users by visual examination or routine testing. Specifically, hazards causing retinal phototoxicity have long been recognized to be associated with the retinal exposure of the light (including, especially, invisible infrared and ultraviolet wavelengths). In addition, FDA requires testing to determine the amount of light emitted and has established maximum exposure levels to mitigate this risk. The potential sight-threatening hazard from retinal phototoxicity due to exposure to the light from the ophthalmoscope cannot be determined without appropriate measurements of the exposure level. The need for special controls has been recognized nationally (American National Standards Institute) and internationally (International Standards Organization). In the near future, FDA intends to propose special controls for the ophthalmoscope and, at the same time, intends to propose to exempt them from the premarket notification requirements. Until the establishment of such controls, however, the characteristics of the device necessary for its safe and effective performance are not well established and changes in the use of the device may result in materially increasing the risk of injury. Accordingly, the device will not presently be exempt from premarket review.

3. *Radiation Oncologist Data Entry Workstation*. Radiation therapy and radiation therapy dose calculation is an exacting procedure. The goal is to maintain the actual dose to within 5 percent of that prescribed. The data entry workstation provides data input to the radiation treatment planning system (RTP) on patient contours and tumor volumes and boundaries. It, therefore, is providing measurement information to the computer that is specific to a particular patient and fundamental to the accuracy of any subsequent treatment planning. As such, the workstation must be regarded as an integral component of the RTP system.

Radiation therapy systems and RTP systems are high-risk devices. Providing an incorrect treatment dose that is too low can result in tumor regrowth. Providing an incorrect treatment dose that is too high can lead to unacceptable complications. Malfunctions of these device types have resulted in patient deaths.

The submission has not provided sufficient information to establish that the characteristics of the device necessary for its safe and effective performance are well established. Further, since that workstation operates by direct connection to the RTP system, it is neither apparent, nor has it been established, that changes in the device that could affect safety and effectiveness or device errors would either: (a) Be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

4. *Cytomegalovirus serological reagents*. Cytomegalovirus infection is the most common identified cause of congenital infection. It has been reported that fewer than 5 percent of these infants develop symptoms during the newborn period. Cytomegalovirus infections are frequent and occasionally severe in children and adults with congenital and acquired cellular immunity defects, such as those with acquired immunodeficiency syndrome (AIDS), in cancer patients (especially those with leukemia), and in those who have received organ transplants. FDA believes that errors caused by these devices could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

5. *Varicella-zoster virus serological reagents*. Varicella-zoster infection may cause severe or fatal disease in individuals who are receiving immunosuppressive therapy or who have an immune response defect. A specific diagnosis of this infection in immunosuppressed individuals may guide the clinician in appropriate therapy. This device would also be useful to evaluate the effect of vaccine in patients. FDA believes that errors caused by these devices could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

Dated: September 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–25916 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 21 and 22, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Walker Room, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tracy K. Riley or Angie Whitacre, Center for Drug