3714) had been jointly filed by Aspen Fiber Corp., P.O. Box 14, Marcell, MN 56657, and Fiber For, Inc., R.D. No. 4, Box 207, Prior Lake, MN 55372. This petition proposed to amend the GRAS regulations in 21 CFR part 582 to affirm that ground whole aspen and ground aspen parts used as a feedstuff for livestock are GRAS.

FDA spoke with a member of the Minnesota Office of Economic Opportunity, Minnesota Department of Economic Security, and a former employee of the Aspen Fiber Corp. Through these sources, FDA determined that Aspen Fiber Corp. has merged with Valley Forest Resources, Inc., HC 1 Box 76, Marcell, MN 56657. Valley Forest Resources agreed, by letter of April 2, 1998, to the withdrawal of the petition. FDA attempted to contact Fiber For, Inc., by letter of January 28, 1998, but that letter was returned as undeliverable. FDA has been unable to locate the firm through directory assistance or the Internet.

The petition is withdrawn based on the letter from Valley Forest Resources, Inc., without prejudice to future filing.

Dated: September 17, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–26085 Filed 9–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 98P–0425, 98P–0506, and 98P–0621]

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 October 30, 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 preamendment 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 postamendment 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)(1) of the act which 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 the 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, 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. Abbott Laboratories, 21 CFR 862.1715 *Triiodothyronine uptake test system devices*.

2. Radiological Imaging Technology, 21 CFR 892.5050, *Film Dosimetry System*, a.k.a. *Film Scanning System*.

3. Getinge/Castle, Inc., 21 CFR 878.4580 *Surgical Lamps*.

IV. Comments

Interested persons may, on or before October 30, 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: September 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–26082 Filed 9–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices 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). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices 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 29, 1998, 8:30 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, ext. 118, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote on a premarket approval supplement for a new indication for an extracorporeal immunoadsorption device intended for the treatment of rheumatoid arthritis.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 22, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9 a.m. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 22, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 22, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–26083 Filed 9–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0777]

Draft Guidance for Industry on Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production.'' The purpose of this draft guidance document is to provide guidance to the pharmaceutical industry on what to do when analytical test results fall outside of specifications (OOS) during pharmaceutical production.

DATES: Written comments on the draft guidance document may be submitted by November 30, 1998. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance document are available on the Internet using the World Wide Web (WWW) at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document 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.

FOR FURTHER INFORMATION CONTACT: C. Russ Rutledge, Center for Drug Evaluation and Research (HFD–325), 7520 Standish Pl., Rockville, MD 20855, 301–594–0098, FAX 301–594–2202.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance document entitled ''Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production.'' This draft guidance document provides guidance to the pharmaceutical industry on how to investigate laboratory test results that fall outside of specification limits. This draft guidance document describes how to investigate results in the laboratory phase, including responsibilities of the analyst and supervisor, and if necessary, expand the investigation outside of the laboratory to include production, processes, and raw materials as appropriate.

This draft level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on OOS test results. 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 requirement of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the draft guidance document to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may