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