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

submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–26084 Filed 9–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel.

Date: October 9, 1998.

Time: 1:00 pm to 3:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn, 5520 Wisconsin Ave, Chevy Chase, MD 20815.

Contact Person Sherry L. Dupere, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5136, MSC 7840, Bethesda, MD 20892, (301) 435–1021.

Name of Committee: Cardiovascular Sciences Initial Review Group, Experimental Cardiovascular Sciences Study Section.

Date: October 19–20, 1998.

Time: 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Anshumali Chaudhari, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4128, MSC 7802, Bethesda, MD 20892, (301) 435–1210.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine, 93.306; 93.333, Clinical Research, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 23, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–26192 Filed 9–29–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Review of Training Grant Applications.

Date: October 13–14, 1998.

Time: October 13, 1998, 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn, 1775 Rockville Pike, Rockville, MD 20852.

Time: October 14, 1998, 8:00 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Ramada Inn, 1775 Rockville Pike, Rockville, MD 20852.

Contact Person: Eric H. Brown, Scientific Review Administrator, NIH, NHLBI, DEA, Rockledge Building II, 6701 Rockledge Drive, Suite 7204, Bethesda, MD C 7956, (301) 435–0299.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Demonstration and Education Research Grant Application (R18s).

Date: October 15, 1998.

Time: 9:00 am to 6:00 pm.

Agenda: To review and evaluate grant applications.

Place: Hilton National Airport Hotel, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Louise P. Corman, Scientific Review Administrator, NIH, NHLBI, DEA, Rockledge Building II, 6701 Rockledge Drive, Suite 7180, Bethesda, MD 20892–7924, (301) 435–0270.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Jackson Heart Study.

Date: October 16, 1998.

Time: 8:00 am to 12:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, 20814.

Contact Person: C. James Scheirer, Chief, Review Branch, DEA, NIH, NHLBI, Rockledge II, 6701 Rockledge Drive, Room 7216, Bethesda, MD 20892–7924, (301) 435–0260.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: September 22, 1998.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 98–26194 Filed 9–29–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Initial Review Group Epidemiology and Prevention Research Subcommittee.

Date: October 6–7, 1998.

Time: 8:30 am to 5:00 pm.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.