[15] Exemption does not apply if used as folders and injectors for soft or foldable IOL's.
[16] Exemption does not apply when indicated for infants.

IV. Comments

Interested persons may, on or before May 4, 1998, submit to the Dockets Management Branch (address above) written comments regarding the 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–2498 Filed 1–30–98; 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). At least one portion of the meeting will be closed 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 regulatory issues.

Date and Time: The meeting will be held on February 12, 1998, 8:30 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms G and H, 5600 Fishers Lane, 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, 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.

Procedure: On February 12, 1998, from 9:30 a.m. to 10:30 a.m., the meeting will be open to the public. 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 February 6, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 6, 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.

Closed Committee Deliberations: On February 12, 1998, from 10:30 a.m. to 5 p.m., FDA staff will present to the committee confidential information regarding present and future device issues. The committee will also hear and review trade secret and/or confidential commercial information on a product development protocol. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4).

FDA regrets that it was unable to publish this notice 15 days prior to the February 12, 1998, Gastroenterology and Urology Devices Panel of the Medical Devices meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2409 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on February 12, 1998, 9:30 a.m. to 5:30 p.m., and February 13, 1998, 9:30 a.m. to 6 p.m.

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

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 12, 1998, the committee will provide advice and recommendations to the agency on issues regarding tests for hepatitis viruses intended for detecting antigens or nucleic acids of hepatitis viruses B and C, or antibodies (total, IgG, or IgM) to antigens of hepatitis viruses A, B, and C. These assays may be indicated for the diagnosis of current (acute or chronic), recent, or past infection; management of current infection; determination of prior immunologic experience or pre- and post-vaccination antibody responses. These devices are not indicated for screening donors of blood or blood products, unless specifically indicated for such uses. The intent of the committee discussion is not to resolve issues related to the clinical practice or treatment of patients with viral hepatitis. Rather, the focus of discussion will be on appropriate clinical studies for establishing the safety and effectiveness of devices for these hepatitis viruses when used for the previously stated indications for use. On February 13, 1998, the committee will discuss a petition for reclassification of fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II.

Procedure: On February 12, 1998, from 9:30 a.m. to 5:30 p.m., and on February 13, 1998, from 10 a.m. to 6

p.m., the meeting is open to the public. 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 February 4, 1998. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11:15 a.m. on February 12, 1998, and between approximately 10:15 a.m. and 10:45 a.m. on February 13, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 4, 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.

Closed Committee Deliberations: On February 13, 1998, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present to the committee trade secret and/or confidential commercial information regarding pending and future device submissions.

FDA regrets that it was unable to publish this notice 15 days prior to the February 12 and 13, 1998, Microbiology Devices Panel of the Medical Devices meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Microbiology Devices Panel of the Medical Devices were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: January 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2465 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies, and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

This Notice is now available on the internet at the following website: http://www.health.org

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, Room 13A–54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443–6014.

SUPPLEMENTARY INFORMATION:

Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–71. Subpart C of the Guidelines, ''Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies,'' sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in a quarterly performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

ACL Laboratory, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840 (formerly: Bayshore Clinical Laboratory)

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615–255–2400

Alabama Reference Laboratories, Inc., 543 South Hull St., Montgomery, AL 36103, 800–541–4931 / 334–263–5745

Alliance Laboratory Services, 3200 Burnet Ave., Cincinnati, OH 45229, 513–569–2051, (formerly: Jewish Hospital of Cincinnati, Inc.)

American Medical Laboratories, Inc., 14225 Newbrook Dr., Chantilly, VA 20151, 703–802–6900

Associated Pathologists Laboratories, Inc., 4230 South Burnham Ave., Suite 250, Las Vegas, NV 89119–5412, 702–733–7866 / 800–433–2750

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801–583–2787 / 800–242–2787

Baptist Medical Center—Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299, 501–202–2783, (formerly: Forensic Toxicology Laboratory Baptist Medical Center)

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Ave., Miami, FL 33136, 305–325–5784

Clinical Reference Lab, 8433 Quivira Rd., Lenexa, KS 66215–2802, 800–445–6917

CompuChem Laboratories, Inc., 1904 Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900 / 800–833–3984, (Formerly: CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Cox Health Systems, Department of Toxicology, 1423 North Jefferson Ave., Springfield, MO 65802, 800–876–3652/417–269–3093, (formerly: Cox Medical Centers)

Dept. of the Navy, Navy Drug Screening Laboratory, Great Lakes, IL, P. O. Box 88–6819, Great Lakes, IL 60088–6819, 847–688–2045 / 847–688–4171

Diagnostic Services Inc., dba DSI, 4048 Evans Ave., Suite 301, Fort Myers, FL 33901, 941–418–1700 / 800–735–5416

Doctors Laboratory, Inc., P.O. Box 2658, 2906 Julia Dr., Valdosta, GA 31604, 912–244–4468

DrugProof, Division of Dynacare/Laboratory of Pathology, LLC, 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 800–898–0180 / 206–386–2672 (formerly: Laboratory of Pathology of