Although the committees provide recommendations to the agency, final decisions are made by FDA.

On November 21, 1997, President Clinton signed the Modernization Act. Section 120 of the Modernization Act amends section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) by adding section 505(n), which pertains to advisory committees that provide scientific advice and recommendations to the agency regarding the clinical investigation of drugs and the approval for marketing of drugs. Section 505(n) of the act includes provisions for: (1) Additional members to be included in new advisory committees, (2) new conflict of interest considerations, (3) education and training for new committee members, (4) timely committee consideration of matters, and (5) timely agency notification to affected persons of decisions on matters considered by advisory committees. This guidance document explains how CDER and CBER intend to change their policies and procedures with regard to advisory committees to implement section 120 of the Modernization Act. Because CDER and CBER advisory committees are organized according to general subject (e.g., blood products, cardiovascular and renal drugs) and not according to the topic for consideration by the committee (e.g., a clinical investigation of a drug product, the content of a guidance document), CDER and CBER generally use the same policies and procedures for all advisory committees, regardless of the topic that will be considered by the committee. Therefore, unless otherwise stated, the guidance applies to CDER and CBER advisory committees regardless of the topic that will be considered by the committee. This guidance document is being issued as a level 1 guidance consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comments from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance represents the agency's current thinking on the advisory committee provisions of section 120 of the Modernization Act. 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 requirements of the applicable statute, regulations, or both.

Interested persons may, on or before January 4, 1999, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies 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 guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29186 Filed 10–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0312]

Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997.'' The FDA Modernization Act of 1997 (FDAMA) codified and expanded the Third Party Review Pilot Program providing for review of certain premarket notification (510(k)) submissions by private parties outside of the Center for Devices and Radiological Health (CDRH). This guidance will assist those who are interested in participating in this program, either as persons accredited to perform 510(k) reviews (Accredited Persons) or as applicants pursuing clearance of 510(k) submissions through use of Accredited Persons, as well as FDA staff responsible for implementing the program.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written comments concerning this guidance to the contact person listed below. If you do not have access to the World Wide Web (WWW), submit written requests for single copies of the guidance entitled ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997'' on a 3.5'' disk, to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, or FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

On August 1, 1996, FDA established the Third Party Review Pilot Program, a voluntary pilot program, to assess the feasibility of using third party reviewers to improve the efficiency of the agency's review of 510(k)'s for selected low-to-moderate risk devices. Under the pilot program, persons required to submit 510(k)'s for the eligible devices were permitted to contract with an FDA Recognized Third Party and submit a 510(k) directly to the third party for review. Persons who did not wish to participate in the pilot continued to submit 510(k)'s directly to FDA.

Under FDAMA, this pilot program has been codified and expanded and FDA is required to establish and publish criteria to accredit or deny accreditation to persons who request to perform third party reviews. Those criteria were published in the **Federal Register** of May 22, 1998 (63 FR 28388). On the same date, the agency announced the availability of a draft guidance pertaining to the third party review program (63 FR 28392). The agency received three comments on the draft guidance. FDA has reviewed the comments and has made some revisions to the guidance in response to the comments. The agency also has included additional information regarding conflicts of interest. This includes additional examples of conditions that could indicate an appearance of a conflict of interest and a statement that applications from prospective third parties should include the written policies and procedures that have been established to ensure that contract employees involved in the evaluation of 510(k)'s are also free from conflicts of interest.

FDA will begin to accept applications from prospective accredited persons beginning July 20, 1998. FDA will

review those applications in 60 days and approved Accredited Persons may begin to submit reviews of 510(k)'s on November 21, 1998. Because Accredited Persons must participate in training prior to submitting recommendations, applicants who wish to attend the initial training that will be held October 14 through 16, 1998, should submit their applications at least 60 days in advance of that date.

II. Significance of Guidance

This guidance represents the agency's current thinking on implementation of the third party review program. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance has been issued under the agency's procedures for a Level 1 guidance document.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may also do so using the WWW. CDRH maintains an entry on the WWW for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH home page includes ''Guidance for Staff, Industry, and Third Parties: Implementation of Third Party Programs Under the FDA Modernization Act of 1997,'' device safety alerts, access to **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers addresses), small manufacturers assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

A text-only version of the CDRH home page is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, at any time, submit written comments regarding this final guidance to the contact person listed above. Comments will be considered when determining whether to amend the current guidance.

Dated: October 26, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–29275 Filed 10–30–98; 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, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014.

Special Note: Our office moved to a different building on May 18, 1998. Please use the above address for all regular mail and correspondence. For all overnight mail service use the following address: Division of Workplace Programs, 5515 Security Lane, Room 815, Rockville, Maryland 20852.

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 Laboratories, 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, 513–585–9000, (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