2. Wednesday, November 18, 1998, from 8:30 a.m. to 3:30 p.m., in Irvine, CA.
3. Friday, November 20, 1998, from 8:30 a.m. to 3:30 p.m., in Oakland, CA.

ADDRESSES: The public meetings will be held at the following locations:

Bellevue—Rockwell Institute, 13218 NE. 20th St., Bellevue, WA 98005.

Irvine—Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92715.

Oakland—Roybal Auditorium, Oakland Federal Bldg., 1301 Clay St., Third Floor Conference Center, Oakland, CA 94612.

FOR FURTHER INFORMATION CONTACT:

Regarding meeting content and format: Mark S. Roh, Small Business Representative, Pacific Region, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3980, FAX 510-637-3977.

Regarding the Bellevue, WA, meeting: Jaimee Hansen, Registration Coordinator, Organization of Regulatory and Clinical Associates (ORCA), P.O. Box 3490, Redmond, WA 98073, 425–487–7179, FAX 425–487–8666.

Regarding the Irvine, CA, meeting: Judy Keast, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3960, FAX 510–637–3976.

Regarding the Oakland, CA, meeting: Judy Keast (address above).

Those persons interested in attending the Bellevue, WA, meeting should register by faxing their name(s), title, firm name, address, telephone, and fax number to Jaimee Hansen (fax number above). This meeting is being conducted in cooperation with a local nonprofit organization, ORCA. There is limited seating, so early registration is encouraged. A registration fee of $45.00 to cover the cost of the facilities for this meeting should be paid to ORCA. Arrangements for payment should be made directly with Ms. Hansen.

Those persons interested in attending the Irvine and/or Oakland, CA, meetings should register by faxing their name(s), title, firm name, address, telephone, and fax number; and date and location of the meeting to Judy Keast (fax number above). There is no registration fee for the Irvine and Oakland meetings. However, seating is limited, so early registration is encouraged.

If you need special accommodations due to a disability, please contact Ms. Hansen (Bellevue meeting) or Ms. Keast (Irvine and Oakland meetings) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The purpose of these meetings is to continue the dialogue, begun in 1996, with members of trade, technical, and professional organizations, and other interested persons on issues associated with pharmaceutical laboratory practices and procedures. The information presented at these meetings will also be appropriate and useful for other industries performing laboratory analysis, including private laboratories and manufacturers of in vitro products.

On November 20, 1996, FDA held a public meeting to informally address and outline ways to discuss problems associated with the development and monitoring of products. The meeting explored issues of concern to the agency and industry laboratories. As a result of the meeting, industry members asked FDA to provide guidance in two control aspects of pharmaceutical production: (1) Evaluating OOS test results, and (2) system suitability requirements in measuring performance of a chromatographic system.

Interested persons who are unable to attend these meetings may submit comments on this topic as well as suggest additional laboratory training issues of interest to FDA regulated industry for future dialogue. Submit written comments to Mark Roh (address above).

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29187 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–0549]

Guidance for Industry on Advisory Committees: Implementing Section 120 of the Food and Drug Administration 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 for industry entitled ''Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997.'' This document provides guidance for industry on changes to the policies and procedures being used by the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) with regard to advisory committees as a result of section 120 of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments on the guidance may be submitted by February 1, 1999. General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.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 this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the address below.

FOR FURTHER INFORMATION CONTACT:

Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5648, or

William Freas, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Advisory Committees: Implementing Section 120 of the Food and Drug Administration Modernization Act of 1997.'' Advisory committees provide independent advice and recommendations to FDA on scientific and technical matters related to the development and evaluation of products regulated by the agency. CDER and CBER request advice from advisory committees on a variety of matters, including various aspects of clinical investigations and applications for marketing approval of drug products.

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