Supplementary Stewardship Reporting exposure draft and also to discuss issues related to the *Accounting for Revenue and Other Financing Sources* exposure draft.

Any interested person may attend the meeting as an observer. Board discussions and reviews are open to the public.

FOR FURTHER INFORMATION CONTACT: Ronald S. Young, Executive Staff Director, 750 First St. NE., room 1001, Washington, DC 20002, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988)); 41 CFR 101–6.1015 (1990).

Dated: January 5, 1996.

Ronald S. Young,

Executive Director.

[FR Doc. 96–397 Filed 1–10–96; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Grassroots Regulatory Partnership Meeting; Pacific Region; Importing Community

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Office of the Pacific Region, Office of External Affairs) is announcing a free public meeting as a followup to a meeting held in April 1995. The FDA Office of the Pacific Region will meet with interested persons in the Pacific Region to improve levels of communication with industries and individuals associated with the importation of FDA regulated commodities, provide improved levels of consumer protection in connection with imported commodities, and to address specific issues related to the importing industry, Pacific Region, and FDA. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of this agency, and to create local partnerships.

DATES: The public meeting will be held on Thursday, January 18, 1996, from 9:30 a.m. to 3 p.m. Registration check-in begins at 9 a.m.

ADDRESSES: The public meeting will be held at the FDA Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92715–2445.

FOR FURTHER INFORMATION CONTACT:

Regarding the Seattle area: George F. Long, Food and Drug Administration, 9935 Pacific Hwy., Blaine, WA 98230, 360–332–4032.

Regarding the San Francisco area: Janet Codor, Food and Drug Administration, 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070, 510–337–6735.

Regarding the Los Angeles area: Mary J. Ayling, Food and Drug Administration, 222 West Sixth St., suite 700, San Pedro, CA 90731, 310–831–6123.

Regarding registration: Maxine K. Fritz or Hetal S. Sutaria, Food and Drug Administration, 19900 MacArthur Blvd., suite 300, Irvine, CA 92715–2445, 714–798–7694 or FAX 714–798–7794.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19573), FDA announced that a series of Grassroots Regulatory Partnership meetings would be held. This document announces a followup meeting to the one held on April 27, 1995, in Burlingame, CA. Those persons interested in attending this meeting should FAX their name(s), affiliation, address, telephone and FAX numbers, and any specific questions they want addressed at the meeting to Maxine K. Fritz or Hetal S. Sutaria (address above). The public meeting is free of charge, however due to space limitations, it will be necessary to check with the registration contact person(s) listed above prior to the meeting to check on space availability. The goals of this meeting are to assist importers, brokers and others associated with a wide variety of products being imported through the Pacific Coast and to listen to concerns and ideas, and to identify next-steps for the agency.

Dated: January 4, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–419 Filed 1–10–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95D–0375]

Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements; 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 Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements.'' This document, which was prepared by the Center for Drug Evaluation and Research (CDER), is intended to provide guidance on how to prepare environmental assessments (EA's) for submission to CDER in new drug applications (NDA's), antibiotic applications, abbreviated new drug applications (ANDA's), abbreviated antibiotic applications (AADA's), and investigational new drug applications (IND's). The guidance fulfills a commitment made in the President's National Performance Report, ''Reinventing Drug and Medical Device Regulations,'' April 1995, to clarify through guidance current EA procedures.

DATES: Written comments on the guidance may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled ''Guidance for Industry for the Submission of an Environmental Assessment in Human Drug Applications and Supplements'' to the Consumer Affairs Branch (formerly the CDER Executive Secretariat Staff), Center for Drug Evaluation and Research (HFD–210), 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your requests. An electronic version of this guidance is also available via Internet by connecting to the CDER file transfer protocol (FTP) server (CDVS2.CDER.FDA.GOV) using the FTP. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), 5600 Fishers Lane, Rockville, MD 20857, 301–594–6740, FAX 301–594–6197, Internet: SAGERN@CDER.FDA.GOV.

SUPPLEMENTARY INFORMATION: NEPA requires all Federal agencies to assess the environmental impacts of their actions and to ensure that the interested and affected public is informed of environmental analyses. FDA is required under NEPA to consider the environmental impact of approving drug product applications as an integral part

of its regulatory process. FDA's regulations in part 25 (21 CFR part 25) specify that EA's or abbreviated environmental assessments (AEA's) must be submitted as part of certain NDA's, antibiotic applications, ANDA's, AADA's, IND's, and for other various actions. This guidance provides information on how to prepare EA's for submission to CDER for these drug product applications. Topics covered in this guidance include: (1) When categorical exclusions apply, (2) when to submit an EA or AEA, (3) the content and format of EA's or AEA's, (4) approaches to determining the environmental fate and effects of substances, (5) test methods, (6) treatment of confidential information submitted in support of an EA, (7) special considerations associated with EA's for genetically altered organisms and materials and products derived from natural sources, (8) EA documentation for foreign manufacturing facilities, and (9) drug master files.

CDER encourages industry to implement the use of the content and format described in this guidance as soon as possible because standardized documentation submitted by industry increases the efficiency and speed of the review process. Alternative content and format styles may be used as long as the regulatory requirements defined in part 25 are satisfied.

Section III.D.7.c of this guidance describes specific circumstances (identified as Tier 0) under which format items 7, 8, 9, 10, 11, and 15 are unnecessary and may be omitted from certain environmental assessments submitted pursuant to § 25.31a(a). Because approval of a product under these circumstances is unlikely to have a significant environmental effect, submission of information for these format items will not ordinarily assist CDER in determining whether an action significantly affects the environment. Therefore, for applications already submitted in which these circumstances exist, the applicant has the option to withdraw the information submitted in format items 7, 8, 9, 10, 11, and 15; and CDER will not review it. The applicant should submit an amendment to the application stating that the circumstances described in Tier 0 exist in the application, and the information is being withdrawn for format items 7, 8, 9, 10, 11, and 15. Because CDER is required to make the EA and a finding of no significant impact (FONSI) publicly available, the applicant should provide, along with the letter, a revised EA with the information in those format items deleted. The applicant should certify that the remaining information has not been revised from what was previously submitted. To avoid unnecessarily complicating the review process if the review has already been completed, the applicant should state in the letter that it waives the request to withdraw this information if CDER has prepared a FONSI based on the previously submitted information. CDER requests that pending applications be amended on or before February 12, 1996. A copy of the amendment cover letter should be sent to the contact person (address above). The applicant has the option of checking with the contact person regarding the status of the environmental review for its pending application. An amendment of this type will not affect the user fee due date required by the Prescription Drug User Fee Act of 1992 (Pub. L. 102–571).

Under the President's reinventing government (REGO) initiatives announced in April 1995, CDER is reevaluating its environmental regulations and plans to reduce the number of EA's required to be submitted by industry and, consequently, the number of FONSI's prepared by the agency under NEPA. FDA will publish in a future issue of the Federal Register a proposed rule concerning proposed additional categorical exclusions for those actions CDER has determined normally do not individually or cumulatively have a significant effect on the quality of the human environment. This guidance explaining how to prepare an EA when required by current regulations will remain in effect until superseded by revised final regulations or new CDER guidance.

Although this guidance does not create or confer any rights, for or on any person, and does not operate to bind FDA, it does represent the agency's current thinking on how to prepare environmental assessments for submission to CDER.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. 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 guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 2, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–420 Filed 1–10–96; 8:45 am]

BILLING CODE 4160–01–F

Investigational Biological Product Trials; Procedure to Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting of the clinical hold review committee, which reviews the clinical holds that the Center for Biologics Evaluation and Research (CBER) has placed on certain investigational biological product trials. CBER held its first clinical hold review meeting on May 17, 1995. FDA is inviting any interested biological product company to use this confidential mechanism to submit to the committee for its review the name and number of any investigational biological product trial placed on clinical hold during the past 12 months that the company wants the committee to review.

DATES: The meeting will be held in February 1996. Biological product companies may submit review requests for the February meeting by January 30, 1996.

ADDRESSES: Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF–7), Food and Drug Administration, rm. 14–105, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

FOR FURTHER INFORMATION CONTACT: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–2), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0379.

SUPPLEMENTARY INFORMATION: FDA regulations in part 312 (21 CFR part 312) provide procedures that govern the use of investigational new drugs and biologics in human subjects. These regulations require that the sponsor of a clinical investigation submit an investigational new drug application (IND) to FDA outlining the proposed use of the investigational product. The IND must contain the study protocol, a summary of human and animal experience with the product, and information on the product's characterization, chemistry, pharmacology, and toxicology. FDA reviews an IND to help ensure the safety and rights of human subjects of research and to help ensure that the quality of any scientific evaluation of a drug is adequate to permit an evaluation of the product's efficacy and safety.