

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.

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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.

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[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:

SAGER@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