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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Control of Pharmaceutical Production; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of three public meetings sponsored by the Office of Regulatory Affairs (ORA), Pacific Region, and participated in by representatives from the Center for Drug Evaluation and Research (CDER), ORA's Division of Field Science, and the Pacific Region. The topic to be discussed is out-of-specification (OOS) laboratory test results, how to evaluate them and appropriate actions to take.

DATES: The public meetings are scheduled as follows:

1. Monday, November 16, 1998, from 8:30 a.m. to 3:30 p.m., in Bellevue, WA.
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
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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

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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.