

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date	7-5-00
Publication Date	7-6-00
Certifier	S. H. Hase

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Office of Regulatory Affairs, Center for Drug Evaluation and Research, and the Central Region Small Business Assistance Office, and the Pacific Region Small Business Office, in cooperation with the International Society for Pharmaceutical Engineering (ISPE) is announcing two workshops entitled FDA/Industry Exchange Workshops on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshops are intended to review the scientific, regulatory, and quality basis of SUPAC; discuss current issues; and provide attendees with information on the impact of the SUPAC guidances that have been finalized, as well as future agency efforts in this area.

Date and Time: See Table 1 following the *Location* section of this document.

Location: See Table 1 below.

TABLE 1

Workshop Address	Date and Local Time
Long Beach Convention Center, 300 East Ocean Blvd., Long Beach, CA 90802.	Tuesday, September 26, 2000, 9 a.m. to 4:30 p.m. Pacific time.
Embassy Suites, 150 Anza Blvd., Burlingame, CA 94010, 650-340-0327.	Friday, December 8, 2000, 9 a.m. to 4:30 p.m. Pacific time.

NMI

Contact: Marcia Madrigal, Industry and Small Business Representative, Food and Drug Administration, Oakland Federal Bldg., 1301 Clay St., suite 1180N, Oakland, CA 94612, 510-637-3980; FAX 510-637-3977 or via e-mail: mmadriga@ora.fda.gov.

Registration: The registration fee is \$295 for ISPE members and \$450 for nonmembers (which will cover refreshments, lunch, and materials). The ISPE tax number is FEI 59-2009272. Contact ISPE for registration forms, and other registration details at ISPE 3816 W. Linebaugh Ave, suite 412, Tampa, FL 33624, 813-960-2105; FAX 813-264-2816, or visit the ISPE website at <http://www.ispe.org>. Registrations are due 1 week prior to the start of each course. Space is limited, therefore, interested parties are encouraged to register early. Limited onsite registration may be available. Please arrive early to ensure prompt registration. Persons needing hotel rooms for the Embassy Suites location on December 8, 2000, should mention that they are attending the FDA/SUPAC workshop. A special rate is available until November 16, 2000, or until the room block is exhausted, whichever comes first.

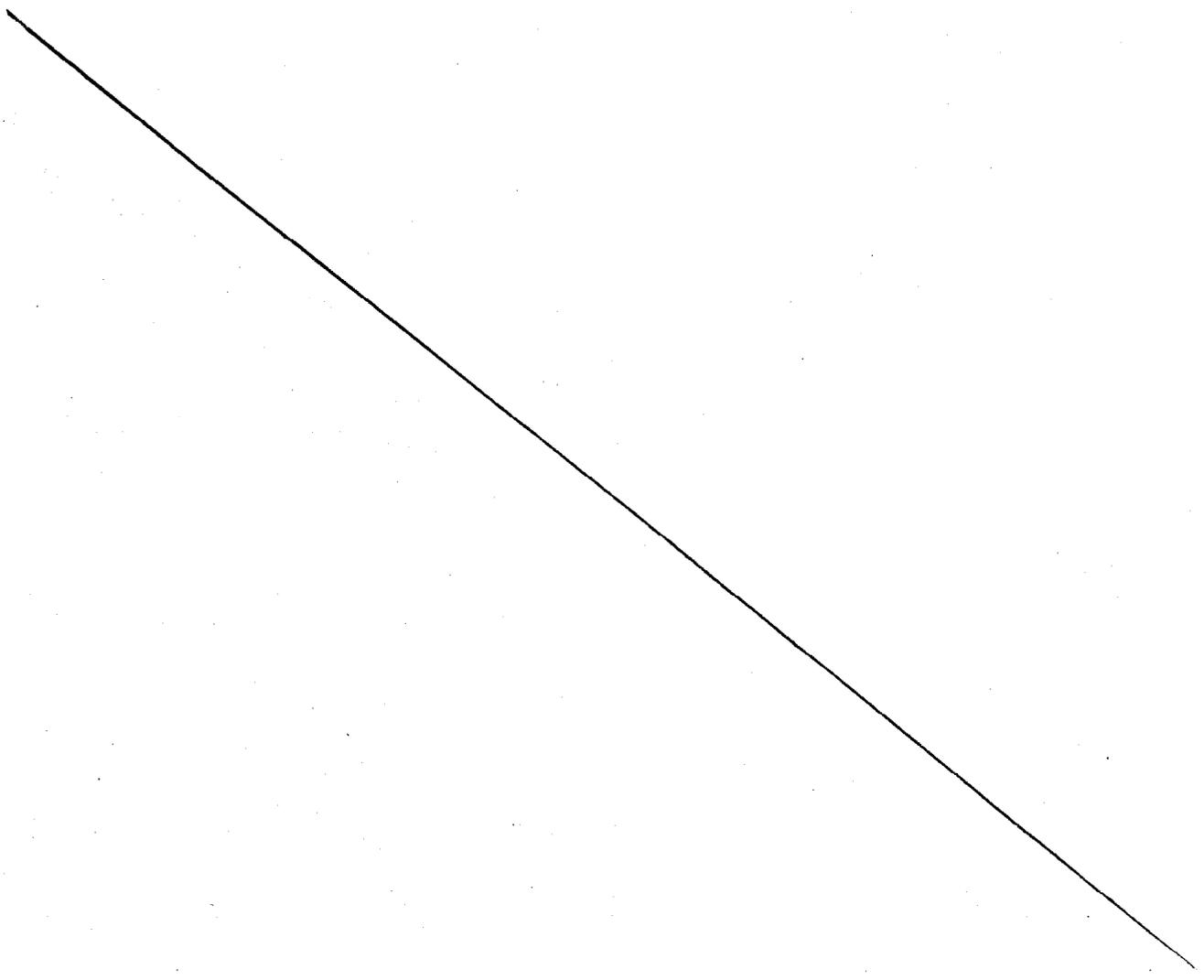
If you need special accommodations due to a disability, please contact ISPE at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshops are designed to help achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C 393) and discussed in the FDA Plan for Statutory Compliance, which include working more closely with stakeholders; maximizing the availability of, and clarifying information about the process for review and submissions; and ensuring access to needed scientific and technical expertise.

The workshops also are consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), as outreach activities by Government agencies directed to small businesses.

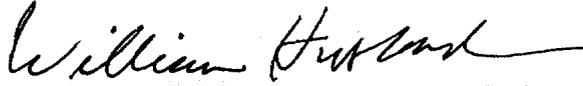
The topics to be discussed include the following: (1) The history of SUPAC development; (2) the impact of scale-up postapproval change guidances and of the regulation rewrite of 21 CFR 314.70 (Supplements and other changes to an approved application); (3) comparison of SUPAC

of SUPAC immediate-release solid dosage forms, modified-release oral dosage forms, and semisolid-topical dosage forms; (4) postapproval changes sterile aqueous solutions; (5) FDA field



staff's involvement in SUPAC; (6) description and use of the equipment addenda to SUPAC; and (7) facts, figures, and future directions.

Dated: June 27, 2000



William K. Hubbard

Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

