

DMB

Display Date	8-2-99
Publication Date	8-3-99
Certifier	SN Reese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Scale-Up and Postapproval Changes, 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 Southeast Region Small Business Assistance Office, in cooperation with the North Carolina Regulatory Affairs Forum (NCRAF) is announcing the following workshop: FDA/Industry Exchange Workshop on Scale-Up and Postapproval Changes (SUPAC), Supplements, and Other Postapproval Changes. The workshop is 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: The workshop will be held on Tuesday, August 17, 1999, from 8 a.m. to 5 p.m. Send information regarding registration by August 10, 1999.

Location: The workshop will be held at the Durham Marriott at the Civic Center, 201 Foster St., Durham, NC 27701, 919-768-6000, FAX 919-768-6037. Persons needing hotel rooms should mention that they are attending the SUPAC workshop. A special rate is available until July 23, 1999.

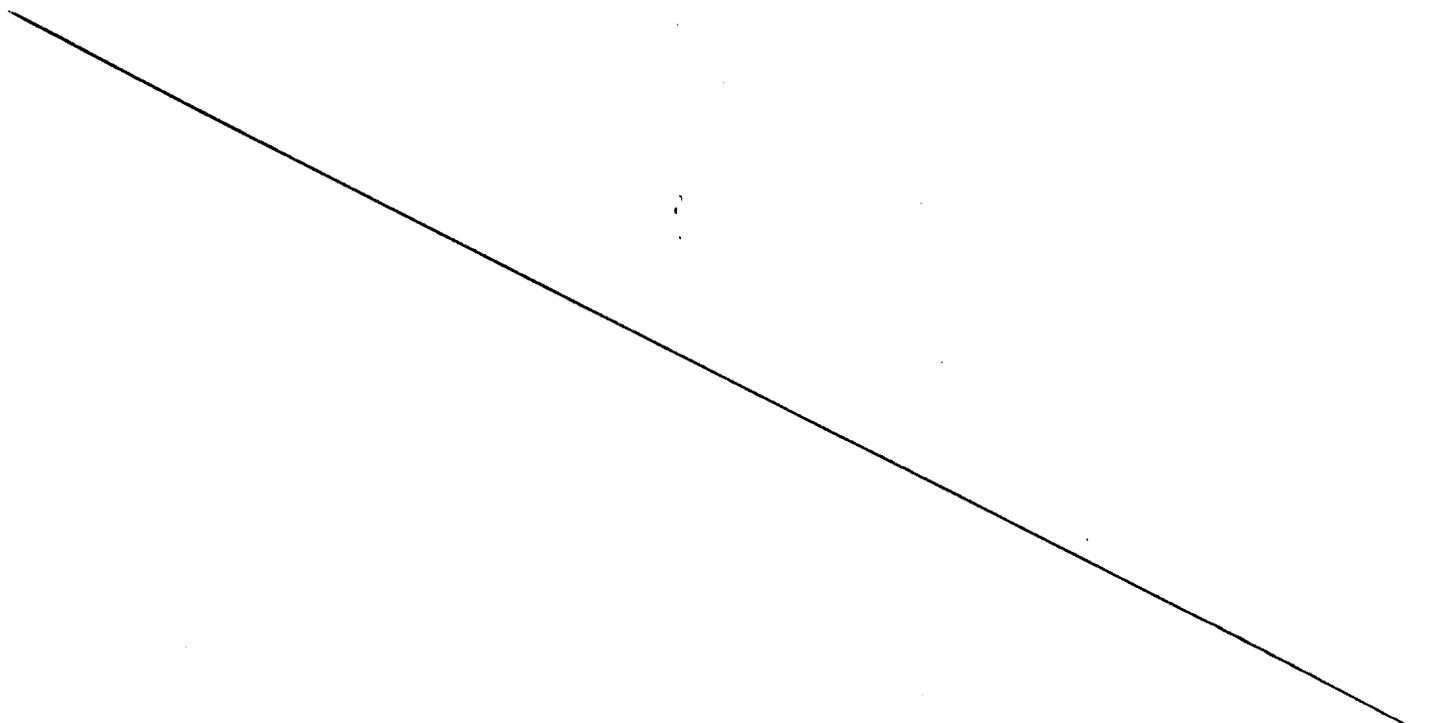
Contact: Barbara Ward-Groves, Industry and Small Business Representative, Food and Drug Administration, 60 Eighth St. NE., Atlanta, GA 30309, 404-253-2238.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number), along with a \$75 check (which will cover refreshments, lunch, and materials) made payable to NCRAF, P.O. Box 13474, Research Triangle Park, NC 27709, c/o Jamie Morgan, 919-845-8055, by August 10, 1999. Space is limited, therefore, interested parties are encouraged to register early. Limited on-site registration may be available. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please contact Jamie Morgan at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop meets the requirements 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.

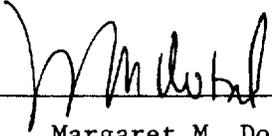
The workshop also complies with the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121) that requires outreach activities by Government agencies directed to small businesses.

The topics to be discussed include the following: (1) The history of SUPAC development; (2) comparison of SUPAC immediate-release solid dosage forms, modified-release oral dosage



forms, and semisolid-topical dosage forms; (3) bulk actives postapproval changes; (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: 7/27/99
July 27, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

