above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this draft guidance also is available via Internet using the World Wide Web (WWW) (connect to cdrh home page at http://www.fda.gov/cdrh/ode/usgudode.pdf).

Dated: June 4, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–15452 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0211]

Guidance for Industry on Nonsterile Semisolid Dosage Forms (SUPAC-SS) for Chemistry, Manufacturing, and Controls; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and abbreviated antibiotic drug applications (AADA's) who intend to change the components or composition, the manufacturing (process and equipment), the scale-up/scale-down of manufacture, and/or the site of manufacture of a semisolid formulation during the postapproval period. This guidance document addresses nonsterile semisolid preparations (e.g., creams, gels, lotions, and ointments) intended for topical routes of administration. This guidance document represents the agency's current thinking on scale-up and postapproval changes for nonsterile semisolid (SUPAC-SS) dosage forms regulated by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Nonsterile Semisolid Dosage Forms; Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation.'' The purpose of this guidance document is to provide insight and recommendations to pharmaceutical sponsors of NDA's, ANDA's, and AADA's who intend to change: (1) The components or composition; (2) the manufacturing (process and equipment); (3) the scale-up/scale-down of manufacture; and/or (4) the site of manufacture of a semisolid formulation during the postapproval period. This guidance document addresses nonsterile semisolid preparations (e.g., creams, gels, lotions, and ointments) intended for topical routes of administration. The guidance document defines the following: (1) Levels of change; (2) recommended chemistry, manufacturing, and controls (CMC) tests to support each level of change; (3) recommended in vitro release tests and/or in vivo bioequivalence tests to support each level of change; and (4) documentation to support the change.

This guidance document represents the agency's current thinking on scale-up and postapproval changes for nonsterile semisolid dosage forms regulated by CDER. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

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

An electronic version of this guidance document is also available on the Internet using the World Wide Web (http://www.fda.gov/cder/guidance.htm).

Dated: June 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–15451 Filed 6–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0418]

Order for Certain Class III Devices; Submission of Safety and Effectiveness Information; Group 3

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising the schedule for submission of summaries and citations for 4 devices included in the order requiring manufacturers of 27 class III devices (Group 3) to submit to FDA a summary of, and a citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices which has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). In response to comments received on the August 14, 1995, order and in order to facilitate the review process, FDA is grouping four cardiovascular devices with related uses together and is changing the date by which summaries and citations are to be submitted to February 14, 1998. The agency is deferring the due date for one gastroenterology-urological device also until February 14, 1998. As a reminder to device manufacturers, FDA is also