report that indicates all materials have been reviewed and approved.

Application Submission and Deadlines

1. Preapplication Letter of Intent

A non-binding letter of intent-to-apply is required from potential applicants. An original and two copies of the letter should be submitted to the Grants Management Branch, Procurement and Grants Office, CDC (see ''Applications'' for the address). It should be postmarked no later than July 14, 1997. The letter should identify announcement number 751, name of principal investigator, and specify the activity to be addressed by the proposed project. The letter of intent does not influence review of funding decisions, but it will enable CDC to plan the review more efficiently, and will ensure that each applicant receives timely and relevant information prior to application submission.

2. Applications

An original and two complete copies of the application, including PHS Form 5161–1 (OMB Number 0937–0189), must be submitted to Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Rd., NE., Rm 300, Mailstop E–15, Atlanta, GA 30305, or before August 7, 1997.

3. Deadlines

a. Applications shall be considered as meeting the deadline if they are either: (1) Received on or before the deadline date; or (2) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

b. Applicants that do not meet the criteria in 3.a.(1) or 3.a.(2) above are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, information on application procedures, an application package and business management technical assistance may be obtained from Van Malone, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Rd., NE., Rm 300, Mailstop E–15, Atlanta, GA, telephone (404) 842–6575, Internet E-mail: vxm7@cdc.gov.

Programmatic technical assistance may be obtained from Bob Kohmescher, Deputy Chief, Behavioral Intervention Research Branch, Division of HIV/AIDS Prevention, National Center for HIV, STD, and TB Prevention, Centers for Disease Control and Prevention (CDC), 1600 Clifton Rd., NE., Mailstop E37, Atlanta, GA 30333, telephone (404) 639–8302, Internet E-mail: rnk1@cdc.gov.

Please refer to Announcement 751 when requesting information and submitting an application.

Potential applicants may obtain a copy of ''Healthy People 2000'' (Full Report, Stock No. 017–001–00474–0) or ''Healthy People 2000,'' (Summary Report, Stock No. 017–001–00473–1) referenced in the ''INTRODUCTION,'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

The announcement will be available on two Internet sites on the publication date: CDC's home page at http://www.cdc.gov, or at the Government Printing Office home page (including free access to the **Federal Register**) at http://www.access.gpo.gov.

Dated: June 9, 1997.

Joseph R. Carter,

Acting Associate Director for Management and Operations, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–15512 Filed 6–12–97; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0209]

Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled, ''Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.'' This draft guidance is intended to assist the manufacturer in preparing a complete 510(k) premarket notification submission to the Center for Devices and Radiological Health (CDRH) or a third party reviewing organization. The agency is seeking public comment on the draft guidance.

DATES: Written comments on the draft guidance document may be submitted by July 28, 1997.

ADDRESSES: Submit written comments and requests for single copies of the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Robert A. Phillips, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20852, 301–594–1212.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is making this draft guidance document available in order to assist manufacturers preparing notification submissions for diagnostic ultrasound systems and transducers. In addition to basic information on submitting a 5l0(k) for these devices, the draft guidance contains specific information on device description, predicate device comparison, acoustic output reporting, general clinical safety and effectiveness, and labeling. The draft guidance also contains information on submitting a post-clearance special report called the ''510(k) special report'' providing production acoustic output values and other information.

A guidance document does not bind FDA or the public, and it does not create or confer any rights, privileges, or benefits for or on any person, however, it does represent the agency's current thinking on the subjects discussed therein. The draft guidance document announced in this notice represents the agency's tentative thinking of the subjects discussed therein.

II. Request for Comments

Interested persons may, on or before July 28, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. 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. Received comments may be seen in the office

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