

FDA-ORA-03-Project I (Inspection)" or "RFA-FDA-ORA-03-Project II (Education and Health Information Dissemination) or "RFA-FDA-ORA-03-Project III (State Laboratories)." You must submit only one project application (an original and two copies) per package.

VII. Method of Application

A. Submission Instructions

You must submit each application under separate cover. Do not submit more than one application (original with 2 copies) per envelope. Applications will be accepted during working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.

Do not send applications to the Center for Scientific Research (CDR), NIH. Any application sent to NIH that is then forwarded to FDA and not received in time for orderly processing will be deemed unresponsive and returned to the applicant. Instructions for completing the application are included in Form PHS-5161-1. FDA is unable to receive applications via the Internet.

B. Format for Application

You must submit the application on Grant Application Form PHS 5161-1 (Rev 7/00). All of the instructions for the enclosed Standard Form 424 (SF424) should be followed using the nonconstruction application pages. A properly formatted sample application for the grant can be accessed on the Internet at http://www.fda.gov/ora/fed_state/Innovative_Grants.html. Applications may be considered nonresponsive if not submitted in the proper order.

The face page of the application should indicate "RFA-FDA-ORA-03-Project I (Inspection)," or "RFA-FDA-ORA-03-Project II (Education and Health Information and Dissemination)" or "RFA-FDA-ORA-03-Project III (State laboratories)."

Data and information included in the application, if identified by the applicant as trade secret will be given treatment as such to the extent permitted by the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on PHS Form 5161-1 were approved and issued under the Office of Management and Budget Circular A-102.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-13594 Filed 5-30-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91D-0407]

Medical Devices; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA." This document describes a means by which resorbable calcium salt bone void filler devices may comply with the requirement for special controls. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to classify the resorbable calcium salt bone void filler device into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-

8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Nadine Y. Sloan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1296.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 7, 2002 (67 FR 5753), FDA published a proposed rule to classify the resorbable calcium salt bone void filler device into class II (special controls). FDA identified the draft guidance document entitled "Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device: Draft Guidance for Industry and FDA" as the special control capable of providing reasonable assurance of safety and effectiveness for these devices.

Interested persons were invited to comment on the draft guidance by May 8, 2002. FDA received three comments. These comments were supportive of the guidance document and made suggestions on the guidance's content. Two of the comments also requested clarification of the scope and the risks in the guidance document. FDA considered the comments and revised the guidance document accordingly. We also clarified our labeling recommendations.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the resorbable calcium salt bone void filler device. 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 requirements of the applicable statute and regulations.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a resorbable calcium salt bone void filler device will need to