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]

BILLING CODE 4160–01–S

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

address the issues covered in the class II special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) . The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this guidance. Submit a single copy of electronic comments or two hard copies of any mailed comments, 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (855) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Dockets Management Branch Internet site at *http://www.fda.gov/ohrms/dockets*.

Dated: April 9, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–13593 Filed 5–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) is submitting a request for review and approval of a collection of information under the emergency processing procedures in Office of Management and Budget (OMB) regulation 5 CFR 1320.13. FEMA is requesting that this information collection be approved by June 23, 2003. The approval will authorize FEMA to use the collection through December 31, 2003. FEMA plans to follow this emergency request with a request for a 3-year approval. The request will be processed under OMB's normal clearance procedures in accordance with the provisions of OMB regulation 5 CFR 1320.10. To help us with the timely processing of the emergency and normal clearance submissions to OMB, FEMA invites the general public to comment on the proposed collection of information.

SUPPLEMENTARY INFORMATION: Executive Order 13254 of January 29, 2002 specifies that ''the executive departments, agencies, and offices constituting USA Freedom Corps shall coordinate and strengthen Federal and other service opportunities, including opportunities for participation in homeland security preparedness and response.'' The Office of Citizen Corps, within the Department of Homeland Security, is the USA Freedom Corps office with lead responsibility for overseeing homeland security, preparedness, and response service opportunities for all Americans.

To better determine the needs, interests, and attitudes of the American public in these realms, it is critical for the Office of Citizen Corps to conduct a survey of a representative sampling of the general public. To date, there is no survey data that pertains specifically to the mission of Citizen Corps to have every American embrace their personal responsibility to be prepared, to get training in first aid and emergency response and to volunteer to support first responders. The results of the survey will be an essential tool to most effectively direct program resources and activities.

Collection of Information

Title: Citizens Corps Individual Survey.

Abstract: The Office of Citizen Corps will conduct a survey of a representative sampling of the public to better determine the needs and interests of the American public in the realms of homeland security, preparedness and response. The results of the survey will enable Citizen Corps to determine future programs and activities.

Type of Information Collection: New collection.

Affected Public: Individuals or households.

Number of Respondents: 2500.

Estimated Total Annual Burden Hours: 417 hours.

Estimated Cost: There are no financial costs associated with the collection of this information. The Office of Citizen Corps has contract support to develop, administer, and analyze this survey. In addition, contract support will develop a communications strategy based on the survey results and analysis to best position the Citizen Corps message for the American public. The estimated costs, including these contractor services, as well as those associated with incidental printing and information delivery, is $140,000.00.

Comments: Written comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and