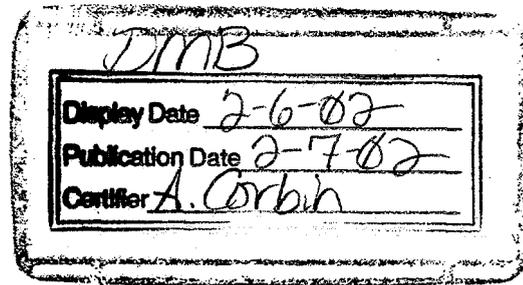


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91 D-04071



Draft Guidance for Industry and FDA on Class II Special Controls Guidance

Document: Resorbable Calcium Salt Bone Void Filler Device; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device." This draft guidance is intended to support the classification of the resorbable calcium salt bone void filler device. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify the resorbable calcium salt bone void filler device into class II. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by [insert *date 90 days after date of publication in the Federal Register*]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" to the Division of Small Manufacturers, International and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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://>

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www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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

This draft guidance was developed as a special control guidance to support the classification of the resorbable calcium salt bone void filler device into class II. FDA is proposing to classify this device elsewhere in this issue of the **Federal Register**. This guidance may not be implemented until the agency completes notice and comment rulemaking to classify the device. If a final rule to classify this device type is not issued, this guidance document will not be issued as a special control.

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the resorbable calcium salt bone void filler device. If the device is classified into class II, a manufacturer who intends to market a device of this generic type must: (1) Conform with the general controls of the Federal Food, Drug, and Cosmetic Act, including the section 510(k) requirements (21 U.S.C. 360(k)) described in 21 CFR 807.81; (2) address the specific risks to health associated with use of the device; and (3) receive a substantial equivalence determination from FDA prior to marketing the device.

The draft guidance identifies the risks to health and serves as a special control that, when followed and combined with the general controls, will generally address the risks associated with this type of generic device.

II. Significance of Guidance

This draft guidance represents the agency's current thinking about 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 an approach satisfies the applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance is issued as a level 1 draft guidance consistent with the GGP regulations.

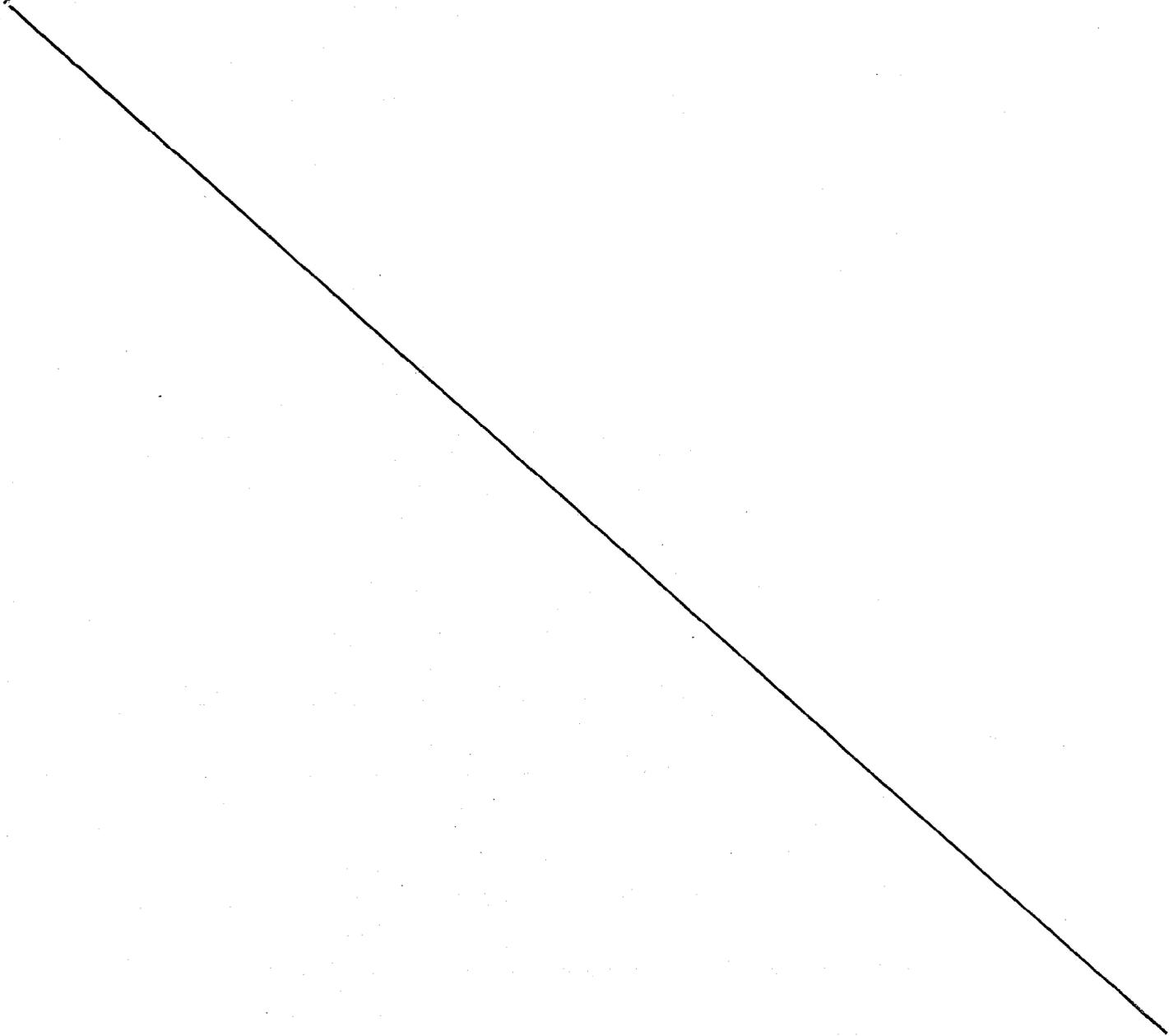
III. Electronic Access

In order to receive "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" via your 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 draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including the text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidances document package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by [*insert date 90 days after date of publication in the Federal Register*]. 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 draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/5/01
October 5, 2001.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health

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[FR Doc. ⁰²01-????? Filed ⁸²??-??-01; 8:45 am]

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