040), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5445.

For information regarding biological products: Karen Weiss, Center for Biologics Evaluation and Research (HFM–570), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1148, 301–827–5093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Available Therapy.'' Available therapy and related terms, such as existing treatments and existing therapy, appear in a number of regulations and policy statements issued by CDER and CBER, but these terms have never been formally defined by the agency. Some confusion has arisen regarding whether available therapy refers only to products approved by FDA for the use in question, or whether it could also refer to products used off-label or to treatments not regulated by FDA, such as surgery. The draft guidance document is intended to inform the public of the agency's interpretation of available therapy.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It represents the agency's current thinking on this topic. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/ohrms/dockets/default.htm, http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm.

Dated: January 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2948 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 91D–0407]

Draft Guidance for Industry and FDA on Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Availability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 May 8, 2002. 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://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 May 8, 2002. 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: October 5, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3018 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0729]

Medical Devices; Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revision to the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submission of Washers and Washer-Disinfectors.'' (63 FR 59794). The revised guidance renamed ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' will serve as a special control for medical washers and medical washer-disinfectors if they are classified into class II. Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to classify medical washers as class II (special controls).

DATES: Submit written or electronic comments 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: Medical Washers and Medical Washer-Disinfectors'' 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Chiu Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION:

I. Background

The intent of this guidance document for class II medical washers and medical washer-disinfectors is: (1) To provide applicants specific directions regarding information and data that should be submitted to FDA in a 510(k) submission for medical washer-disinfectors intended to clean and provide high level disinfection, and (2) to provide recommendations on information and data to be held as part of the design control record for a medical washer intended to clean medical devices or a medical washer-disinfector intended to clean and provide either a low or intermediate level of disinfection for medical devices. The General Hospital and Personal Use Devices Advisory Panel met on September 14, 1998, and unanimously recommended that the medical washer and washer-disinfector be classified into class II.

FDA made the draft guidance entitled ''Guidance on the Content and Format of Premarket Notification (510(k)) Submissions of Washers and Washer-Disinfectors'' available for comment on November 5, 1998 (63 FR 59794). The public comment period closed February 3, 1999. FDA reviewed the comments and revised the draft guidance as appropriate. The final guidance renamed ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' replaces the November 5, 1998, draft.

II. Significance of Guidance

This guidance document represents the agency's current thinking on medical washers and medical washer-disinfectors. 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 applicable statute and regulations.

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

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors'' 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