DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on March 12, 2002, from 8 a.m. to 5 p.m.

Location: CDER Advisory Committee Conference Room, Rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Thomas H. Perez or Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by phone at 301–827–7001, or by e-mail at PerezT@cder.fda.gov or TopperK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss potential conflicts of interest in pediatric oncology clinical trials, off-protocol patient access to investigational drugs, and access to investigational drugs for nonclinical studies.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by March 4, 2002. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 12:45 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 4, 2002, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Thomas H. Perez or Kimberly Littleton Topper at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 31, 2002.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 02–2950 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

2002 FDA Science Forum

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: 2002 FDA Science Forum. The topic to be discussed is ''FDA: Building a Multidisciplinary Foundation.''

Date and Time: The science forum will be held on February 20 and 21, 2002, from 8:30 a.m. to 4:30 p.m.

Location: The science forum will be held at the Washington Convention Center, 900 Ninth St. NW., Washington, DC 20001.

Contact: AOAC International, Fulfillment Department, 301–924–7077, e-mail: fulfillment@aoac.org, or Donna L. Mentch, Food and Drug Administration, Office of Science (HF–33), 5600 Fishers Lane, Rockville, MD 20857, 301–827–3038, e-mail: dmentch@oc.fda.gov.

Registration: Attendees may register onsite on February 20 and 21, 2002. Registration and program information are also available at http://www/aoac.org/science.htm. Attendance will be limited; therefore, interested parties are encouraged to register early.

SUPPLEMENTARY INFORMATION: The 2002 FDA Science Forum will focus on the importance of FDA's many scientific and regulatory disciplines to the agency's decisionmaking process. On the first day speakers and participants will address the role of research and review in the formulation of FDA's public health policies. The second day will feature the principles of public health surveillance and the relation of surveillance to current scientific issues, from both domestic and global perspectives.

If you need special accommodations due to a disability, please contact AOAC International at least 7 days in advance.

Dated: February 1, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–3021 Filed 2–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0582]

Draft Guidance for Industry on Available Therapy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Available Therapy.'' The document is intended to provide guidance to industry on the meaning of the term available therapy, as used by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit written or electronic comments on the draft guidance by April 8, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), 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 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 document.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drug products: Janet Jones, Center for Drug Evaluation and Research (HFD–

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