a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. The guidance supplements recommendations regarding IDE and IND submissions contained in other FDA publications. The guidance announced in this notice finalizes the draft guidance of the same title dated July 2007.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–(800) 835–4709 or (301) 827–1800; or by calling CDRH at 1–(800) 638–2041 or by faxing a request to CDRH at (301) 847–8149. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lori Jo Churchyard, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, (301) 827–6210; or Elizabeth L. Frank, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, rm. 1407, Silver Spring, MD 20993, (301) 796–5650.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Preparation of IDEs and INDs for Products Intended to Repair or Replace Knee Cartilage'' dated December 2011. The guidance document provides sponsors of an IDE or an IND recommendations about certain information that should be included in a submission describing a product intended to repair or replace knee cartilage. The guidance does not apply to prostheses such as unicondylar or total knee implants, or meniscus replacement products. Human cells, tissues, and cellular and tissue-based products (HCT/P's) regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR part 1271 are beyond the scope of this guidance. A product intended to repair or replace knee cartilage may include a biologic, device, or combination product (comprised of two or more different types of regulated constituents) whose components would individually be regulated by CBER and CDRH. The guidance addresses issues that may arise in the development of articular cartilage repair or replacement products. The guidance supplements other FDA publications on IDEs and INDs that may be relevant to development of these products.

In the **Federal Register** of July 9, 2007 (72 FR 37245), FDA announced the availability of the draft guidance of the same title dated July 2007. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. In response to comments, changes incorporated in the guidance included adding new sections and clinical study schedules, elaborating on nonclinical data considerations, and updating the references. In addition, organizational and editorial changes were made to improve clarity. Some terminology was changed to harmonize terminology within the Agency and does not change the intent of the guidance. The guidance also reflects input received from the public and the Cellular, Tissue, and Gene Therapy Advisory Committee meeting held on May 15, 2009. The guidance announced in this notice finalizes the draft guidance dated July 2007.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA'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. Paperwork Reduction Act of 1995

The guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm, or http://www.regulations.gov.*

Dated: January 11, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–828 Filed 1–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Pediatric Therapeutics, is announcing a public workshop entitled ''Ethical and Regulatory Challenges in the Development of Pediatric Medical Countermeasures.'' There is a critical need for pediatric research on medical countermeasures to ensure that these products are safe and effective in the pediatric population. The challenges to developing and evaluating drugs, biologics, and devices for children in the medical countermeasure context are complex

and need to be better understood by ethicists, researchers, policymakers, and the general public. The purpose of the public workshop is to provide a forum for careful consideration of scientific, ethical, and regulatory issues confronting FDA and other stakeholders in the area of medical countermeasures and public health preparedness.

Date and Time: The public workshop will be held on February 15, 2012, from 8:30 a.m. to 5 p.m. and February 16, 2012, from 8:30 a.m. to 3 p.m.

Location: The public workshop will be held at the Rockville Hilton Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Cindy de Sales, (240) 316–3207, FAX: (240) 316–3201, email: *cindy@tepgevents.com.*

Registration: Please use the following Web site to register online: *http://www.contractmeetings.com.* Alternatively, you can email or fax your registration information (including name, title, firm name, address, telephone and fax numbers) to the contact person by February 1, 2012. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Cindy de Sales (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: The workshop will include plenaries and breakout sessions on the ethical and regulatory challenges in the development of medical countermeasures for the pediatric population. Topics of the breakout sessions will include: (1) Institutional Review Board preparedness to review study protocols relevant to pediatric medical countermeasures; (2) potential scientific and ethical justifications for conducting *pre-event* pediatric medical countermeasures research; (3) leveraging new technologies to develop pediatric medical countermeasures; and (4) risk communication related to pediatric treatment and research during public health emergencies. The workshop also will include discussion of a number of case studies to facilitate discussion of the challenges of pediatric medical countermeasure development and deployment.

Transcripts: Transcripts of the public workshop may be requested in writing from the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, approximately 15 working days after the public workshop at the cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.regulations.gov,* Docket No. FDA–2011–N–0002. Transcripts may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 12, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–846 Filed 1–17–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board Ad hoc Subcommittee on Global Cancer Research.

Open: February 27, 2012, 6:30 p.m. to 8 p.m.

Agenda: Discussion on Global Cancer.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Contact Person: Dr. Ted Trimble, Executive Secretary, NCAB Ad hoc Subcommittee on Global Cancer Research, National Cancer Institute, National Institutes of Health, 6130 Executive Boulevard, EPN/7025, Rockville, MD 20892–8345, (301) 496–2522, *trimblet@mail.nih.gov.*

Name of Committee: National Cancer Advisory Board.

Open: February 28, 2012, 9 a.m. to 3:30 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: February 28, 2012, 3:30 p.m. to 5 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Name of Committee: National Cancer Advisory Board.

Open: February 29, 2012, 9 a.m. to 12 p.m.

Agenda: Program reports and presentations; business of the Board.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892–8327, (301) 496–5147.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)