Products Reporting Program'' (the MedWatch Program).

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 16, 2005 (70 FR 48157), FDA announced that a proposed collection of information entitled ''MedWatch: Food and Drug Administration Medical Products Reporting Program'' had been submitted to OMB for approval under the PRA. The collection of information included the use of two forms used in the MedWatch Program—Form FDA 3500 and Form FDA 3500A. In that notice, we responded to public comments pertaining to proposed revisions to Form FDA 3500 and Form FDA 3500A. Several comments from industry stated that considerable resources would be required to modify computer systems and processes to begin using the mandatory reporting form—Form FDA 3500A. In response to these comments, we stated: ''[T]o allow mandatory reporters time to make the necessary changes to their computer systems and processes to conform to the revised Form FDA 3500A, FDA is granting a grace period of 1 year. During this transition period FDA will accept both the newly effective Form FDA 3500A and the prior version of the form.''

In the **Federal Register** of December 7, 2005 (70 FR 72843), FDA announced that OMB had approved the information collection for the MedWatch Program as submitted to OMB on August 16, 2005. In that notice, we stated: ''As requested by the agency, in addition to the approval of the revised forms, the existing forms are approved for continued use for the next 12 months to allow for the industry to make necessary changes to their computerized systems.'' In response to several recent requests from industry that we grant more time to make necessary changes to computerized systems, we requested and OMB has agreed to extend approval to use the prior version of Form FDA 3500A until May 1, 2007. The expiration date for the newly revised Form FDA 3500A remains unchanged—October 31, 2008. The prior version of Form FDA 3500A is available for downloading at *http://www.fda.gov/medwatch/getforms.htm*, and the expiration date on the form has been revised to May 1, 2007.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: October 19, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–17907 Filed 10–25–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Dental Products Panel of the Medical Devices 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). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Dental Products Panel of the Medical Devices Advisory Committee.

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

*Date and Time*: The meeting will be held on November 9, 2006, from 8 a.m. to 5 p.m.

*Location*: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

*Contact Person*: Michael J. Ryan, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext. 175, e-mail at: *michael.ryan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512518. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: The committee will discuss, make recommendations, and vote on a premarket approval application for a collagen material, which contains a bone morphogenetic protein, for oral maxillofacial bone grafting procedures. Background information, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panel* (click on Upcoming CDRH Advisory Panel/Committee Meetings).

*Procedure*: On November 9, 2006, from 8:30 a.m. to 5 p.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 2, 2006. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before November 2, 2006.

*Closed Committee Deliberations*: On November 9, 2006, from 8 a.m. to 8:30 a.m., the meeting will be closed to the public to permit FDA to present to the committee trade secret and/or confidential commercial information regarding pending and future agency issues (5 U.S.C. 552b(c)(4)) for the next year.

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 AnnMarie Williams, Conference Management Staff, 301–827–7291, at least 7 days in advance of the meeting.

FDA regrets that it was unable to publish this notice 15 days prior to the Dental Products Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Dental Products Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: October 23, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E6–17932 Filed 10–25–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Pediatric 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 Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 21 CFR 50.54 and 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

*Date and Time*: The meeting will be held on November 16, 2006, from 8 a.m. to 4 p.m.

*Location*: Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person*: Jan Johannessen, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–6687, e-mail: *Jan.Johannessen@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

*Agenda*: The Pediatric Advisory Committee will hear and discuss a report by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act, on adverse event reports for ertapenem (INVANZ), gemcitabine (GEMZAR), glimepiride (AMARYL), insulin aspart recombinant (NOVOLOG), linezolid (ZYVOX), meloxicam (MOBIC), ondansetron (ZOFRAN), oxcarbazepine (TRILEPTAL), ritonavir (NORVIR), rosiglitazone (AVANDIA), sirolimus (RAPAMUNE). The committee will also receive updates to adverse event reports for atorvastatin (LIPITOR), citalopram (CELEXA), oseltamivir (TAMIFLU), oxybutynin (DITROPAN), and simvastatin (ZOCOR), which were requested by the Pediatric Advisory Committee or its predecessor, the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee, when the reports were first presented.

The background material will become available no later than 1 business day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2006 and scroll down to Pediatric Advisory Committee link.)

*Procedure*: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 1, 2006. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. on November 16, 2006. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person 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 on or before by November 1, 2006.

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 Jan N. Johannessen 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: October 23, 2006.

**Randall W. Lutter,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E6–17965 Filed 10–25–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2006D–0408]**

### Draft Guidance for Industry and Food and Drug Administration Staff; Annual Reports for Approved Premarket Approval Applications; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Annual Reports for Approved Premarket Approval Applications.'' This draft guidance document outlines the information required by a certain FDA regulation in periodic reports (usually referred to as annual reports) and FDA's recommendations for the level of detail that manufacturers should provide. This draft guidance is not final nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by January 24, 2007. Submit written or electronic comments on the collection of information by December 26, 2006.

**ADDRESSES:** Submit written requests for single copies of the draft guidance document entitled ''Annual Reports for Approved Premarket Approval Applications'' 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the collection of information to the Division of Dockets Management (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.

**FOR FURTHER INFORMATION CONTACT:**

*For device issues*: Laura Byrd, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

*For biologics issues*: Leonard Wilson,