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,

Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document outlines the information required by § 814.84(b) (21 CFR 814.84(b)) in periodic reports (usually referred to as annual reports) and FDA's recommendations for the level of detail that manufacturers should provide. We also outline the principles and procedures that the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) follow when we review these reports, identify the steps FDA staff generally take when reviewing annual reports, the resources available to assist staff in conducting their reviews, and the possible outcomes of a review. This draft guidance is not final nor is it in effect at this time.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Annual Reports for Approved Premarket Approval Applications.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Annual Reports for Approved Premarket Approval Applications'' you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number (1585) to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including 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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60–day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Annual Reports for Approved Premarket Approval Applications.

Description: Devices subject to premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) are also subject to periodic reports imposed by the premarket approval application (PMA) approval order (§ 814.82(a) (21 CFR 814.82(a)) and § 814.84(b)). FDA typically specifies that an applicant submit a report 1 year from the date of approval of the original PMA and annually thereafter. Therefore the periodic report is usually referred to as the annual report. Although this draft guidance addresses ''annual reports,'' there may be circumstances where FDA specifies more frequent periodic reports. FDA believes this draft guidance will also be relevant to the more frequent reports.

This draft guidance document describes FDA's recommendation for the level of detail that should be provided in the annual report. This draft guidance suggests that an annual report should include a cover letter that includes the following information: (1) PMA number; (2) device name (including any model names and numbers); (3) company name; (4) date of report; (5) reporting period; and (5) approval date.

This draft guidance recommends that the annual report also include information regarding manufacturing, design, or labeling changes made during the reporting period, in which the following information should be included: (1) The change made; (2) the rationale for making the change; (3) any validation or other testing that was performed, including a description of the method and acceptance criteria; and (4) the implementation date. This guidance recommends creating a separate table for manufacturing changes, design changes, and labeling changes. Furthermore, if any manufacturing, design, or labeling change is associated with any written communication to practitioners or patients, this draft guidance recommends that the applicant include a copy of the communication in the annual report.

For manufacturing, design, or labeling changes not reported in a PMA Supplement or a 30-day notice, this draft guidance recommends including a brief summary of the risk analysis performed to assess the effect of the changes made during the reporting period. If the risk analysis was performed in conformance to any consensus standards, these should be identified. If system-level testing of the cumulative changes were not conducted, then the risk analysis should also assess whether incremental testing was adequate to assure continued safety and effectiveness of the device in the absence of system level testing. If any changes to the design, manufacture, or labeling that have been made during the reporting period are associated with medical device reporting requirements, failures, or recalls of any kind, corrective actions (21 CFR 820.100), complaints, or in response to FDA warning letters or inspection findings

(FDA Form 483), this draft guidance recommends that the applicant do the following: (1) Describe their investigation of the cause or source of the problem; and (2) explain their decision to change the device design, labeling, or manufacturing process by describing how the actions taken have corrected the problem and mitigated the harm.

This draft guidance also recommends including a discussion of how the results and conclusions in clinical investigations or nonclinical laboratory studies or reports in scientific literature could impact the known safety and effectiveness profile of the device. If changes to the device or its labeling are based on clinical investigations or nonclinical laboratory studies or reports in scientific literature, this draft guidance recommends informing FDA of a plan for submitting a PMA Supplement or 30-day notice for these changes; or in the alternative, explaining why such a submission is not appropriate.

To help FDA assess the public health impact of the information provided in annual reports, this draft guidance also asks applicants to provide data about the number of devices shipped or sold during the reporting period. For device implants, data regarding the number of devices actually implanted should be provided, if it is available.

Finally, this draft guidance suggests that a redacted copy of the annual report may be provided in order to be publicly posted on FDA's Web site.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §§ 814.82(a)(7) and 814.84(b) have been approved under OMB Control No. 0910–0231.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Information Collection Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Annual Report Cover Letter	434	1	434	0.5	217
Rationale for Changes	434	1	434	3	1,302
Summary of Risk Analysis	434	1	434	4	1,736
Evaluation of Clinical Investigations, Non-Clinical Laboratory Studies, or Scientific Literature	434	1	434	7	3,038
Information on Devices Shipped, Sold, or Implanted	434	1	434	5	2,170
Redacted Copy of Annual Report	434	1	434	4	1,736
Total	434	1	434	29.5	10,199

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The industry-wide burden estimate is based on an FDA actual average fiscal year (FY) annual rate of receipt of 434 annual reports, using FY 2003 through 2005 data. The burden data for annual reports is based on FDA estimates.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Dated: October 17, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–17908 Filed 10–25–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Cancellation: Change of Meeting Date

AGENCY: Health Resources and Services Administration; HHS.

ACTION: Meeting notice: cancellation and change of meeting date.

SUMMARY: The Health Resources and Services Administration published a document in the **Federal Register** of September 22, 2006, regarding a meeting date for the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children. The meeting scheduled for November 2–3, 2006, has been cancelled.

Correction

In the **Federal Register** of September 22, 2006, in FR Doc. 06–8018, on page 55494, correct the ''Dates and Times'' section to read:

Dates and Times: December 18, 2006, 9 a.m. to 5 p.m., December 19, 2006, 8:30 a.m. to 3 p.m.

Place: Hilton Washington Hotel, Monroe Room, 1919 Connecticut Avenue, NW., Washington, DC 20009.

Dated: October 20, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. E6–17931 Filed 10–25–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Health Information National Trends Survey 2007 (HINTS 2007)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on