Dated: July 20, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–14750 Filed 7–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

General and Plastic Surgery Devices 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). The meeting will be open to the public.

Name of Committee: General and Plastic Surgery Devices 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 August 25 and 26, 2005, from 8 a.m. to 6 p.m on both days.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: David Krause, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–3090, ext. 141, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512519. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 25, 2005, the committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. On August 25 and 26, 2005, the committee will discuss and make recommendations on the classification of five preamendments medical devices: Bone wax, medical maggots, medicinal leeches, tissue expander, and wound dressing with a drug. Background information for this meeting, including the agenda and questions for the committee, will be made available at least 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

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 by August 11, 2005. On August 25, 2005, oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m., 1:45 p.m. and 2:15 p.m., and 4:30 p.m. and 5 p.m. On August 26, 2005, oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10 a.m., 1 p.m. and 1:30 p.m., and 3:45 p.m. and 4:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before 5 p.m. on August 11, 2005, 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 AnnMarie Williams at 240–276–0450, ext. 113, 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: July 20, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–14749 Filed 7–26–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0261]

Draft Guidance for Industry on Nucleic Acid Testing for Human Immunodeficiency Virus Type 1 and Hepatitis C Virus: Testing, Product Disposition, and Donor Deferral and Reentry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry,'' dated July 2005. The draft guidance document provides information for blood and plasma establishments, manufacturers, and testing laboratories that are implementing a licensed method for NAT on pooled or individual samples of human blood and blood component donations for HIV–1 ribonucleic acid (RNA) and HCV RNA. The draft guidance document is intended to encourage more effective testing of whole blood and blood component samples, and improved product and donor management based on the results of NAT and concurrent serologic testing for markers of HIV and HCV infection on donated whole blood and blood components.

DATES: Submit written or electronic comments on the draft guidance by October 25, 2005 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance 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*.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for

Industry: Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV–1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry'' dated July 2005. There has been a dramatic reduction during the past decade in the transmission of HIV–1 and HCV by human blood and blood components. The reduction is a result of the implementation of sensitive tests for viral antibody, antigen (for HIV–1), and nucleic acids, and the use of effective virus removal and inactivation methods. The sources of remaining risk of HIV–1 and HCV transmission are marker-negative ''window period'' donations, donors infected with immunovariant viral strains, persistent antibody-negative (immunosilent) carriers, and laboratory test procedure errors. Because donations during the window period constitute most of the risk of HIV–1 and HCV transmission, measures to close the ''window period'' further could reduce significantly the low residual risk of HIV–1 and HCV transmission by human blood and blood components. Studies using seroconversion panels indicate the value of NAT in reducing the ''window period'' for HIV–1 and HCV.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 requirement of the applicable statutes and regulations.

II. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. 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 the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: July 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14746 Filed 7–26–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ADDERALL XR (mixed salts of a single-entity amphetamine product), AVANDIA (rosiglitazone), AVAPRO (irbesartan), RAPAMUNE (sirolimus), and ZOFRAN (ondansetron). These summaries are being made available consistent with section 9 of the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337, e-mail: *carmouzeg@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for ADDERALL XR (mixed salts of a single-entity amphetamine product), AVANDIA (rosiglitazone), AVAPRO (irbesartan), RAPAMUNE (sirolimus), and ZOFRAN (ondansetron). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A of the act, permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at *http://www.fda.gov/cder/pediatric/index.htm*, summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ADDERALL XR (mixed salts of a single-entity amphetamine product), AVANDIA (rosiglitazone), AVAPRO (irbesartan), RAPAMUNE (sirolimus), and ZOFRAN (ondansetron). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: July 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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