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The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic.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The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time.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may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance.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 A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.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.

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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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