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]
BILLING CODE 4160–01–S

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 ZOFFRAN (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 summaries 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 ZOFFRAN (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.

[FR Doc. 05–14747 Filed 7–26–05; 8:45 am]