III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: March 17, 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 PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (the 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.

In addition, the agency is also announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies for the following antidepressants: CELAXA (citalopram), REMERON (mirtazapine), SERZONE (nefazodone), PAXIL (paroxetine), and ZOLOFT (sertraline). Studies for these drugs were submitted before the BPCA was implemented. Therefore, they are not subject to its requirements. However, due to the public's interest in these pediatric studies, FDA asked the sponsors to consent to the public disclosure of a summary of the medical and clinical pharmacology reviews for these studies. Based on sponsors' consent, FDA is making the summaries publicly available.

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. As discussed in greater detail in the following paragraphs, section 9 of the BPCA (Public Law 107–109) requires the disclosure of certain summaries of pediatric study reviews. In addition, based on the sponsors' consent, FDA is making available summaries of medical and clinical pharmacology reviews for pediatric studies of antidepressants submitted in response to a written request.

The summaries of medical and clinical pharmacology reviews of pediatric studies conducted for PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine) are being made available consistent with section 9 of the BPCA. 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 (the 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 (*http://www.fda.gov/cder/pediatric/index.htm*) summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for PARAPLATIN (carboplatin), TRUSOPT (dorzolamide), CAMPTOSAR (irinotecan), PREVACID (lansoprazole), TAMIFLU (oseltamivir), VIOXX (rofecoxib), FERRLECIT (sodium ferric gluconate), IMITREX (sumatriptan), DETROL and DETROL LA (tolterodine). Copies are also available by mail (see **ADDRESSES**).

In addition, the agency is also announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies for the following antidepressants: CELAXA (citalopram), REMERON (mirtazapine), SERZONE (nefazodone), PAXIL (paroxetine), and ZOLOFT (sertraline). Section 9 of the BPCA does not require the disclosure of these summaries. However, due to the public's interest in these studies, FDA asked the sponsors to consent to the public disclosure of the summaries of the medical and clinical pharmacology reviews. Based on the sponsors' consent, FDA is making the reviews publicly available on the Internet (*http://www.fda.gov/cder/pediatric/index.htm*) and 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: March 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the