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Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/cber/guidelines.htm*, or *http://www.fda.gov/ohrms/dockets/default.htm*.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

[FR Doc. 05–5977 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

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.

[FR Doc. 05–5974 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

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

Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Free Clinic—FTCA Deeming Application (OMB No. 0915–0293, Extension)

Congress legislated FTCA medical malpractice protection for free clinic volunteer health professionals through Section 194 of the Health Insurance Portability and Accountability Act (HIPAA), amending Section 224 of the Public Health Service Act. Individuals eligible to participate in this program are health care practitioners volunteering at free clinics who meet specific eligibility requirements. If an individual meets all the requirements of this program they can be ''deemed'' to be a Federal employee. This deemed status is specifically to provide immunity from medical malpractice lawsuits as a result of the performance of medical, surgical, dental, or related activities within the scope of the volunteer's work at the free clinic.

The sponsoring free clinic entity must submit an application to the Health Resources and Services Administration (HRSA). This application will require information about the sponsoring free clinic's credentialing system, risk management practices, and quality assurance system in order to ensure the Government is not exposed to undue liability resulting from the medical malpractice coverage of non-qualified health care professionals. Attached to the application will be a listing of specific health care providers for whom the sponsoring free clinic is requesting deemed status.

Estimates of annualized reporting burden are as follows:

Type of form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
FTCA Deeming Application	150	1	150	16	2,400
Total	150		150		2,400

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Kraemer, Health Resources and Services Administration, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 21, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–5972 Filed 3–25–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[DHS–2005–0015]

Privacy Act of 1974; System of Records; Correction

AGENCY: Office of the Secretary, DHS.

ACTION: Notice; correction.

SUMMARY: The Department of Homeland Security (DHS) is correcting a notice that was published in the **Federal Register** on March 22, 2005, at 70 FR 14477 which gives notice that the Bureau of Immigration and Customs Enforcement (ICE) proposes to add a new system of records to the Department's inventory of record systems. The system of records is the Student and Exchange Visitor Information System. In the Heading of the notice, DHS inadvertently mislabeled the DHS docket number associated with the notice. DHS would like to announce that the DHS docket number for submitting comments to this notice is DHS–2005–0015. Directions for submitting comments using this method are outlined within 70 FR 14477.

DATES: This correction is effective March 28, 2005.

FOR FURTHER INFORMATION CONTACT: Jeff Ament, Department of Homeland Security Regulatory Coordinator, Department of Homeland Security, Washington, DC 20528, (202) 205–8088.

SUPPLEMENTARY INFORMATION:

Need for Correction

As published in the **Federal Register** on March 22, 2005 (70 FR 14477), the notice contains an error that is in need of correction.

Correction of Publication

Accordingly, the publication on March 22, 2005 (70 FR 14477), is corrected as follows:

1. On page 14477, in the heading, third line, the new DHS docket number should read: ''DHS Docket Number DHS–2005–0015''

Mary Kate Whalen,

Deputy Associate General Counsel for Regulations, Office of the General Counsel, U.S. Department of Homeland Security.

[FR Doc. 05–6051 Filed 3–23–05; 4:33 pm]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4975–N–07]

Notice of Proposed Information Collection: Comment Request

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 27, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Wayne_Eddins@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly J. Miller, Director, Office of Asset Management, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–3730 (this is not a toll free number) for copies of the