

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, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6460, Silver Spring, MD 20993-0002, 301-796-0700, e-mail: grace.carmouze@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for ALTACE (ramipril), GEMZAR (gemcitabine), LESCOL (fluvastatin), SANDOSTATIN LAR (octreotide), and SEREVENT (salmeterol). 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 (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 at <http://www.fda.gov/cder/pediatric/index.htm> summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for ALTACE (ramipril), GEMZAR (gemcitabine), LESCOL (fluvastatin), SANDOSTATIN LAR (octreotide), and SEREVENT (salmeterol). 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: October 10, 2006.

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 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: National Health Service Corps Travel Request Worksheet (OMB No. 0915-0278): Extension

Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program use the Travel Request Worksheet to receive travel funds from the Federal Government to perform pre-employment interviews at sites on the Approved Practice List. The travel approval process is initiated when a scholar notifies the NHSC's In-Service Support Branch of an impending interview at one or more NHSC approved practice sites.

The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar has successfully been matched to an approved practice site. Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the NHSC contractor regarding authorization of the funding for the relocation.

The burden estimate for the project is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Worksheet	250	2	500	.06	30

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

Dated: October 6, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Notice of Program Exclusions

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.