ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled, ''Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV.'' This guidance is intended to encourage the development of various configurations of previously approved antiretroviral products for the treatment of HIV. The guidance addresses the agency's current thinking regarding the types of information that should be provided in an application seeking approval for FDC, co-packaged, or single-entity products for the treatment of HIV.

The draft version of this guidance, entitled ''Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV,'' was issued in May 2004. The guidance has been updated to address public comments to the draft version. Significant changes to the draft are as follows: (1) The inclusion of single-entity versions, in addition to combination products, in the expedited FDA review pathway; (2) the addition of tables that supply references supporting the clinical efficacy and safety of antiretroviral combinations; and (3) clarification on the amount and type of data that should be submitted in a drug application to support approval or tentative approval.

Combination therapy is essential for the treatment of HIV/AIDS. At least three active drugs, usually from two different classes, are required to suppress the virus, allow recovery of the immune system, and reduce the emergence of HIV resistance. In the United States and developing countries, the availability of a wide range of antiretroviral drug products, including simplified HIV regimens in the form of co-packaged drugs (such as blister packs) or FDCs may facilitate distribution of antiretroviral therapies and improve patient adherence to the regimens.

Although there are more than 20 unique antiretroviral drugs approved in the United States, only a few are approved for use as FDC products, and none are approved as co-packaged products. Some antiretrovirals should not be combined because of overlapping toxicities and potential viral antagonism. Other antiretrovirals should not be used in pregnant women and other special populations. Therefore, it is important that possible combinations of these products be evaluated for safety and efficacy in the populations that may have need of them.

Recently, newer FDCs and single-entity products that have not been approved by FDA have received attention, and some are being promoted for use in resource poor nations where HIV/AIDS has reached epidemic proportions. These products may offer cost advantages or allow simplified dosing. However, the safety, efficacy, and quality of many of these products have not been evaluated by FDA. Products whose safety, efficacy, and quality do not conform to expected standards may pose a threat to individual patients by increasing the chances of substandard performance, which may lead not only to treatment failure, but also to the development and spread of resistant virus.

FDA is prepared to move swiftly to evaluate such products when applications for them are submitted for approval. This guidance clarifies what regulatory requirements would be applied to such applications, what issues might be of concern, and how these should be addressed. Different considerations apply depending on whether a sponsor owns or has a right of reference to all of the data required to support an application or whether a sponsor plans to rely on literature or FDA's findings of safety and effectiveness for an approved drug. Where appropriate, this guidance addresses the issues associated with these different situations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on FDC, co-packaged, and single-entity products for treating HIV infection. 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 requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single comment 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 brackets in the heading of this document. Received comments may be seen 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 document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 11, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–17324 Filed 10–17–06; 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 ALTACE (ramipril), GEMZAR (gemcitabine), LESCOL (fluvastatin), SANDOSTATIN LAR (octreotide), and SEREVENT (salmeterol). 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.

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.

[FR Doc. E6–17284 Filed 10–17–06; 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: 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.

[FR Doc. E6–17318 Filed 10–17–06; 8:45 am]

BILLING CODE 4165–15–P

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.