Officer, CMS, Lord Baltimore Drive, Mail Stop LB–23–20, Baltimore, Maryland 21244; Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider CMS' decision to disapprove Minnesota State plan amendment (SPA) 05–015B which was submitted on September 28, 2005. This SPA was disapproved on June 12, 2006.

Under this SPA, the State proposed to limit incurred medical and remedial care expenses protected under the post eligibility process only to those expenses incurred while an individual is eligible for Medicaid.

Sections 1902(a)(17), and 1902(a)(51) in conjunction with section 1924 of the Social Security Act (the Act), as these sections are refined by section 1902(r)(1), require States to take into account, under the post eligibility process, amounts for incurred medical and remedial care expenses that are not subject to payment by a third party. Section 1902(r)(1)(A)(ii) of the Act and Federal regulations at 42 CFR 435.733(c)(4)(ii) permit States to place ''reasonable'' limits on the amounts of necessary medical and remedial care expenses recognized under State law but not covered under the State plan. The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter.

The issues to be decided in the hearing are:

• Whether Minnesota's SPA 05–015B impermissibly limits the amount of incurred expenses which may be deducted from an institutionalized individual's income for purposes of the post eligibility process by limiting these expenses to those incurred when the individual was Medicaid eligible; and

• Whether allowing this limitation undermines the protection of expenses which can be incurred when an individual is not Medicaid eligible, which must be considered for purposes of the medically needy spend down.

Section 1116 of the Act and Federal regulations at 42 CFR Part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. CMS is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing, and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as *amicus curiae* must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The notice to Minnesota announcing an administrative hearing to reconsider the disapproval of its SPA reads as follows:

Ms. Christine Bronson,
Medicaid Director,
Minnesota Department of Human Services,
P.O. Box 64983,
St. Paul, MN 55164–0983.

Dear Ms. Bronson: I am responding to your request for reconsideration of the decision to disapprove the Minnesota State plan amendment (SPA) 05–015B, which was submitted on September 28, 2005, and disapproved on June 12, 2006.

Under this SPA, the State proposed to limit incurred medical and remedial care expenses protected under the post eligibility process only to those expenses incurred while an individual is eligible for Medicaid.

Sections 1902(a)(17), and 1902(a)(51) in conjunction with section 1924 of the Social Security Act (the Act), as these sections are refined by section 1902(r)(1), require States to take into account, under the post eligibility process, amounts for incurred medical and remedial care expenses that are not subject to payment by a third party. Section 1902(r)(1)(A)(ii) of the Act and Federal regulations at 42 CFR 435.733(c)(4)(ii) permit States to place ''reasonable'' limits on the amounts of necessary medical and remedial care expenses recognized under State law but not covered under the State plan. The amendment was disapproved because CMS found that the amendment violated the statute for reasons set forth in the disapproval letter.

The issues to be decided at the hearing are:

• Whether Minnesota's SPA 05–015B impermissibly limits the amount of incurred expenses which may be deducted from an institutionalized individual's income for purposes of the post eligibility process by limiting these expenses to those incurred when the individual was Medicaid eligible; and

• Whether allowing this limitation undermines the protection of expenses which can be incurred when an individual is not Medicaid eligible, which must be considered for purposes of the medically needy spend down.

I am scheduling a hearing on your request for reconsideration to be held on December 4, 2006, at 233 N. Michigan Avenue, Suite 600, the Illinois Room, Chicago, IL 60601, to reconsider the decision to disapprove SPA 05–015B. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed by Federal regulations at 42 CFR part 430.

I am designating Ms. Kathleen Scully-Hayes as the presiding officer. If these arrangements present any problems, please contact the presiding officer at (410) 786–2055. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the presiding officer to indicate acceptability of the hearing date that has been scheduled and provide names of the individuals who will represent the State at the hearing.

Sincerely,

Mark B. McClellan, M.D., PhD

Section 1116 of the Social Security Act (42 U.S.C. section 1316); (42 CFR section 430.18).

(Catalog of Federal Domestic Assistance program No. 13.714, Medicaid Assistance Program.)

Dated: October 5, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–17368 Filed 10–17–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0228]

Guidance for Industry on Fixed Dose Combinations, Co-Packaged Drug Products, and Single-Entity Versions of Previously Approved Antiretrovirals for the Treatment of HIV; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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.'' The guidance is intended to encourage sponsors to submit to FDA applications for fixed dose combination (FDC), co-packaged, and single-entity versions of antiretroviral drugs for the treatment of human immunodeficiency virus (HIV). The availability of a wide range of safe and effective antiretroviral products may help facilitate a wider distribution of anti-HIV drugs to better meet the demands of the global HIV/AIDS pandemic.

DATES: Submit written or electronic comments on agency guidances at any time.

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.