In accordance with the provisions of this notice, we have determined the amounts of the FY 2004 and FY 2005 redistributed allotment funds to eliminate the FY 2007 shortfalls in SCHIP funding available to shortfall States effective immediately upon publication of this notice. These FY 2004 and FY 2005 redistributed allotment funds are subject to final adjustment based on comments received in response to this notice.

Authority: (Section 1102 of the Social Security Act (42 U.S.C. 1302) (Catalog of Federal Domestic Assistance Program No. 93.767, State Children's Health Insurance Program))

Dated: February 16, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 26, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–2607 Filed 5–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Title V Section 510 Abstinence Education Grant Program-Annual Program Application and Annual Performance Progress Report.

OMB No.: 0970–0271 (formerly 0915–0291 when in HRSA).

Description: The Title V Section 510 Abstinence Education Grant Program (Section 510 program) is a formula block grant program, authorized through June 30, 2007, by the Tax Relief and Health Care Act of 2006.

The Section 510 *Annual Program Application* requires basic application information that will be used by the Administration for Children and Families (ACF) to establish applicant eligibility, determine each applicant's compliance with Federal law, review and evaluate each applicant's proposed plans, and to develop any conditions to be placed on grant awards. Projects must meet the legislative priorities as described in Section 510 of Title V of the Social Security Act.

The Section 510 *Annual Performance Progress Report* includes four forms through which grantees report basic performance information, which is used by ACF to determine each grantee's compliance with Federal law and to review and evaluate each applicant's progress toward achieving its goals. Basic performance information includes the unduplicated count of clients served, hours of service received by clients, program completion data, and communities served.

Respondents: The 50 States, the District of Columbia, and the following 8 Territories: American Samoa, Guam, Republic of the Marshall Islands, Federated States of Micronesia, Commonwealth of the Northern Mariana Islands, Republic of Palau, Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annual Program Application	59	1	40	2,360
Annual Performance Progress Report	59	1	130	7,670

Estimated Total Annual Burden Hours: 10,030.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocolleciotn@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 20, 2007.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 07–2628 Filed 5–25–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0420]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 28, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: FDA Desk Officer, FAX: 202–395–6974. All comments should be identified with the OMB control number 0910–0167. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857,301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Orphan Drugs (OMB Control Number 0910–0167)—Extension

Sections 525 through 526 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the applications under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

The information requested from respondents represents, for the most part, an accounting of information already in the possession of the applicant. It is estimated, based on frequency of requests over the past 5 years, that 171 persons or organizations per year will request orphan-drug designation and none will request formal recommendations on design of preclinical or clinical studies.

In the **Federal Register** of October 30, 2006 (71 FR 63325), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment related to the information collection.

(Comment 1) The comment suggested that our burden estimate to prepare an Orphan Drug Annual Report is too low.

(Response 1) Section 316.30 pertains to annual reporting, a brief progress report which is a requirement after orphan designation has been granted to a sponsor. We estimate this takes 1 hour professional time and 1 hour support time.

(Comment 2) The comment suggested that our estimate of 130 hours to prepare and submit an orphan drug application is too high.

(Response 2) We disagree with the comment because some sponsors have more experience with submitting Orphan Drug Designation applications/requests and, therefore, may require less human resource hours to compile all required information. Many other sponsors, which include foreign sponsors, do not have such experience.

The estimated 130 hours pertains to §§ 316.20, 316.21, and 316.26. These apply primarily to initial applications/requests seeking orphan drug designation. Many applications/requests received in the Office of Orphan Products Development contain multiple volumes; include an exact duplicate copy of the original; and may include 50 or more documented references. Additional information is requested when an application/request is denied. The sponsor usually supplies the requested information in the form of an amendment.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Responses	Total Hours
316.10, 316.12, & 316.14	5	1	5	130	650
316.20, 316.21, & 316.26	171	2	342	130	44,460
316.22	30	1	30	2	60
316.27	25	1	25	4	100
316.30	500	1	500	2	1,000
316.36	.2	3	.6	15	9
Total					46,279

[1] There are no capital costs or maintenance costs associated with this collection of information.

Dated: May 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–10271 Filed 5–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0193]

Timed-Release Drug Products Containing Guaifenesin; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action against unapproved drug products in timed-release dosage forms containing guaifenesin and persons who cause the manufacture or interstate shipment of such products. Hundreds of unapproved drug products in timed-release form containing guaifenesin, alone or in combination with other ingredients, are marketed to relieve the symptoms associated with cough, cold, and similar conditions. Such drug products require approved applications because they are not generally recognized as safe and effective for these uses. One firm has obtained approved applications to market timed-release products containing guaifenesin. Other firms who wish to market a drug product in timed-release form containing guaifenesin must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA).

DATES: This notice is effective May 29, 2007.

For marketed, unapproved drug products in timed-release form containing guaifenesin that have a National Drug Code (NDC) number that is listed with FDA under section 510 of the act (21 U.S.C. 360) on the effective date of this notice (i.e., ''currently marketed products''), the agency intends to exercise its enforcement discretion to permit products properly marketed with those NDC numbers a brief period of continued marketing after May 29, 2007 as follows. FDA does not intend to initiate enforcement actions against firms that are manufacturing such currently marketed products unless those firms are still manufacturing the products on or after August 27, 2007. Further, FDA does not intend to initiate enforcement actions related to the shipment in interstate commerce of currently marketed products made by such firms unless they are still being shipped on or afterNovember 26, 2007. Unapproved drug products in timed-release form containing guaifenesin that are not currently marketed products on the date of this notice must, as of the date of this notice, have approved applications prior to their shipment in interstate commerce. Submission of an application does not excuse timely compliance with this notice.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 2007N–0193 and directed to the appropriate office listed as follows:

Regarding applications under section 505(b) of the act (21 U.S.C. 355(b)): Division of Pulmonary and Allergy Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Regarding applications under section 505(j) of the act: Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

All other communications: Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8964, e-mail: *sakineh.walther@FDA.HHS.GOV*.

SUPPLEMENTARY INFORMATION:

I. Background

Guaifenesin is an expectorant that has been marketed for decades. Thousands of products intended to relieve symptoms associated with cough, colds, allergies and similar conditions are marketed containing guaifenesin, alone or in combination with other active ingredients, such as antitussives (for instance, dextromethorphan or hydrocodone), nasal decongestants (for instance, pseudoephedrine or phenylephrine), and analgesics (for instance, acetaminophen). These products are marketed both over-the-counter (OTC) and by prescription, and in immediate- and timed-release dosage forms.

Guaifenesin in immediate-release form was reviewed in the OTC drug review and is covered by the OTC monograph in part 341 (21 CFR part 341), ''Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use.'' OTC products that comply with this monograph may be marketed without approval.

The OTC monograph system does not include timed-release drug products, a dosage form that is designed to release the active ingredients over a prolonged period of time. Since 1959, the agency has stated that all products in timed-release dosage forms also described as, for example, sustained release, extended release, controlled release, or long-acting—are new drugs requiring approved applications (24 FR 3756, May 9, 1959). Agency review of individual applications is needed to ensure that the finished product releases its active ingredients at a rate that is both safe, without ''dumping'' of the dose, and effective, sustaining the intended effect over the entire period during which the therapeutic benefit is claimed. Firms submitting applications are required to establish appropriate release specifications supported by clinical evidence, along with data showing that the finished product as manufactured by the firm releases its active ingredient according to these specifications. The agency's determination that all products in timed-release form are new drugs requiring approved applications is codified in § 310.502(a)(14) (21 CFR 310.502(a)(14)). The regulation applies to all products in this dosage form containing guaifenesin, alone or in combination with other active ingredients.

II. Current Status of Timed-Release Drug Products Containing Guaifenesin

One firm has obtained approved applications for products in timed-release dosage forms containing guaifenesin. Adams Respiratory Therapeutics, formerly known as Adams Laboratories, Inc. (Adams), submitted an NDA for single-ingredient guaifenesin tablets in timed-release form (NDA 021–282), which was approved by FDA on July 12, 2002. These products are sold OTC under the trade names of MUCINEX (600 milligrams (mg)) and HUMIBID (1,200 mg), with labeling for uses consistent with expectorant products marketed under an OTC monograph (§ 341.78(b)). Specifically, MUCINEX and HUMIBID are intended to help ''loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, and make coughs more productive.'' On October 11, 2002, the agency notified firms marketing single-