I am responding to your request for reconsideration of the decision to disapprove Ohio State plan amendments (SPAs) 05–07 and 05–020, which were submitted on August 1, 2005, and September 1, 2005, respectively, and disapproved on October 28, 2005.

Under SPAs 05–07 and 05–020, Ohio was seeking to implement the Medicaid School Program.

The amendments were disapproved because they did not comport with the requirements of section 1902(a) of the Social Security Act (the Act) and implementing regulations. The specific reasons for disapproval are identified below.

Under section 1902(a)(10) of the Act, a State plan must provide for making medical assistance available to eligible individuals. ''Medical assistance,'' as defined in section 1905(a) of the Act, does not include habilitation services. After the Centers for Medicare & Medicaid Services (CMS) determined that habilitation services were not properly included within the scope of the statutory category of rehabilitation services, the Omnibus Budget Reconciliation Act of 1989 (OBRA–89) ''grandfathered'' certain States, including Ohio, to provide habilitation services under previously approved State plan provisions as part of the Medicaid rehabilitation benefit. However, Ohio formally terminated its habilitation services (known as the ''Community Alternative Funding System,'' or CAFS program) in SPA 05–008 and, thus, is no longer ''grandfathered'' based on its previously approved State plan provision. Because there is no provision of the State's Medicaid plan as approved on or before June 30, 1989, that provides coverage of habilitation services in the State's current approved plan, the provisions of section 6411(g)(1)(A) of OBRA–89, that prohibit the Secretary from withholding, suspending, disallowing, or denying Federal financial participation for habilitation services, no longer apply.

In addition, the SPAs do not comply with the requirements of section 1902(a)(1) of the Act that services under the plan be available statewide. Under the SPAs, services would be covered only for select groups of students in participating schools but services would not be available to other eligible individuals. Because not all parts of the State may have participating schools, the SPAs violate statewideness requirements. The restricted availability of services also violates the requirements of section 1902(a)(10)(B) of the Act that services available to each individual within a Medicaid eligibility group must be comparable in amount, duration, and scope (and that services available to categorically needy groups cannot be less in amount, duration, and scope than those available to the medically needy). The SPAs are not consistent with comparability requirements because the services are available only to select groups of students.

Additionally, these SPAs explicitly deny the provision of Medicaid fair hearing requests for individuals who are denied services. This provision is at variance with section 1902(a)(3) of the Act and Federal regulations at 42 CFR 431.200(a) which require that a State plan ''provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.''

In addition, the State did not demonstrate that the proposed payment methodology would comply with the statutory requirements of sections 1902(a)(2), 1902(a)(30)(A), and 1903(a)(1) of the Act, which require that the State plan assure adequate funding for the non-Federal share of expenditures from State or local sources; that State or local sources have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care; and that Federal matching funds are only available for actual expenditures made by States for services under the approved plan. The State did not respond fully to CMS' requests for information concerning State payment and funding issues. Absent such information, CMS could not determine whether the proposed SPA would operate in compliance with all applicable requirements of section 1902(a) of the Act.

Finally, for Ohio SPA 05–020 alone, the State did not show compliance with section 1902(a)(4) of the Act, which specifies that the State plan must provide for such methods of administration as are found by the Secretary to be necessary for the proper and efficient administration of the plan. Pursuant to this provision, States must include in their State plans all information necessary for CMS to determine whether the plan can be approved to serve as a basis for Federal financial participation. Absent information on the methodology used to develop the fee schedules, this requirement is not met.

For the reasons cited above, and after consultation with the Secretary, as required by 42 CFR 430.15(c)(2), Ohio SPAs 05–07 and 05–020 were disapproved.

I am scheduling a hearing on your request for reconsideration to be held on February 28, 2006, at Suite #500, 233 N. Michigan Avenue, Minnesota Conference Room, Chicago, IL 60202, to reconsider the decision to disapprove SPA 05–07 and 05–020. 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 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, MD., PhD.

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

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

Dated: January 13, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–788 Filed 1–23–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0396]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

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 February 23, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail,

including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level—(OMB Control Number 0910–0430)—Extension

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions (§ 10.75 (21 CFR 10.75)) and dispute resolution during the investigational new drug (IND) process (21 CFR 312.48) and the new drug application/abbreviated new drug application (NDA/ANDA) process (21 CFR 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB Control No. 0910–0014), 314 (OMB Control No. 0910–0001), and part 601 (21 CFR part 601) (OMB Control No. 0910–0338), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

Agency regulations (§§ 312.23(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB Control No. 0910–0014, expires January 31, 2006; and FDA Form 356h, OMB Control No. 0910–0338, expires August 31, 2005.

In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for two reasons: To ensure that each request is kept in the administrative file with the entire underlying application and to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biological product regulated by the agency under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Provided in table 1 of this document is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately 8 sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately 1 respondent submits requests for formal dispute resolution to CBER annually.

The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 10 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 88 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

In the **Federal Register** of October 24, 2005, (70 FR 61453), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received on this information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	8	1.25	10	8	80
CBER	1	1	1	8	8
Total					88

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

Dated: January 13, 2006.

Jeffrey Shuren,

Assistant Commssioner for Policy.

[FR Doc. E6–763 Filed 1–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0021]

Agency Information Collection Activities; Proposed Collection; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the regulations which state that protocols for samples of biological products must be submitted to the agency.

DATES: Submit written or electronic comments on the collection of information by March 27, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Request for Samples and Protocols (OMB Control Number 0910–0206)—Extension)

Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), FDA may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot along with the protocols showing the results of applicable tests prior to marketing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols