I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action.'' This draft guidance provides recommendations to applicants planning product quality studies to document BA or BE in support of NDAs or ANDAs for locally acting drugs in nasal aerosols and nasal sprays. This guidance addresses BA and BE studies of prescription corticosteroids, antihistamines, anticholinergic drug products, and the over-the-counter (OTC) mast-cell stabilizer cromolyn sodium. The guidance does not address studies of nasal sprays included in applicable OTC monographs or studies of: (1) Metered-dose products intended to deliver drugs systemically via the nasal route, or (2) drugs in nasal nonmetered dose atomizer (squeeze) bottles that require premarket approval.

Because many substantive changes were made to the guidance after it issued in 1999, the guidance is being reissued at this time for comment as a level 1 draft guidance. We encourage applicants to submit any evidence that supports or refutes the approaches outlined in this guidance to the docket number given in brackets in the heading of this document.

The changes made were based on the following: (1) Public comments submitted to the original docket, (2) the outcome of April 2000 and July 2001 meetings of the Orally Inhaled and Nasal Drug Products Subcommittee of the FDA Advisory Committee for Pharmaceutical Science (ACPS), (3) a July 2001 meeting of the ACPS, and (4) internal discussions within the Center for Drug Evaluation and Research. Changes include reduction in the recommended extent of in vitro testing, elimination of two of the three options for rhinitis study design, and elimination of the recommendation to demonstrate a dose-response relationship from the recommended rhinitis study design (traditional 2-week study). The latter two changes are based on ACPS recommendations. A section on reserve samples for BA and BE testing has also been added. The statistical information that was previously part of the original draft has now been consolidated into appendices that will be published at a later date.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on BA and BE product quality information related to nasal inhalation aerosols and nasal metered-dose spray pumps. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. Alternative approaches to documentation of BA and BE may be used if such approaches satisfy the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch written or electronic comments regarding this document. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be indentified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Dockets Management Branch 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: March 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8010 Filed 4–2–03; 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, 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: The Uniform Progress Report (UPR) for HRSA Continuation Training Grants (OMB No. 0915–0061)—Revision

The HRSA Progress Reports for Continuation Training Grants are used for the preparation and submission of continuation applications for Titles VII and VIII health professions and nursing education and training programs. The Uniform Progress Report measures grantee success in meeting (1) the objectives of the grant project and (2) the cross-cutting outcomes developed for the Bureau's education and training programs. Part I of the progress report is designed to collect information to determine whether sufficient progress has been made on the approved project objectives, as grantees must demonstrate satisfactory progress to warrant continuation of funding. Part II collects information on activities specific to a given program. Part III, Comprehensive Performance Management System, collects data on overall project performance related to the Bureau of Health Professions' strategic goals, objectives, outcomes and indicators. Progress will be measured based on the objectives of the grant project and outcome measures and indicators developed by the Bureau to meet requirements of the Government Performance and Results Act (GPRA).

To respond to the requirements of GPRA, the Bureau developed goals, outcomes and indicators that provide a framework for collection of outcome data for its Titles VII and VIII programs. An outcome-based performance system is critical for measuring whether program support is meeting national health workforce objectives. At the core of the performance measurement system are found cross-cutting goals with respect to workforce quality, supply, diversity and distribution of the health professions workforce. A demonstration project to assess availability of the data needed to support the indicators was conducted, and data from this project are currently being analyzed.

The grantees were able to obtain and submit progress reports electronically for fiscal year 2001.

The burden estimate is as follows:

Form	Number of respondents	Response per respondent	Total responses	Hours per response	Total burden hours
Progress Report	1,550	1	1,550	21.5	33,325

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

Dated: March 27, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–8012 Filed 4–2–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Migrant Health; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Migrant Health.

Dates and Times: April 30, 2003, 9:30 a.m. to 5 p.m., May 1, 2003, 8:30 a.m. to 12 noon.

Place: San Carlos Hotel, 202 North Central Avenue, Phoenix, Arizona 85004, Phone: (602) 253–4121 Fax (602) 253–6668.

Status: The meeting will be open to the public.

Agenda: The agenda includes an overview of general Council business activities and priorities. Topics to be addressed will include orientation of new Council members and restructuring subcommittees. In addition, the Council will begin preliminary work on the 2003 recommendations to the Secretary. Finally, the Council will attend the National Association of Community Health Centers' 2003 National Farmworker Health Conference, which is also being held in Phoenix at this time. Agenda items are subject to change as priorities indicate.

For Further Information Contact: Anyone requiring information regarding the Council should contact: Benito Velazquez or Gladys Cate, Migrant Health Program, staff support to the National Advisory Council on Migrant Health, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone (301) 594–4064.

Dated: March 27, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–8013 Filed 4–2–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: Request for Generic Clearance To Conduct Voluntary Customer/Partner Surveys

SUMMARY: Under the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Library of Medicine (NLM), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on, December 6, 2002, in Volume 67, No. 235, page 72692 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Library of Medicine may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection

Title: Voluntary Customer Satisfaction Surveys.

Type of Information Collection Request: Extension. OMB Control No. 0925–0476, with an expiration date of March 31, 2003.

Need and Use of Information Collection: Executive Order 12962 directs agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. Additionally, since 1994, the NLM has been a ''Federal Reinvention Laboratory'' with a goal of improving its methods of delivering information to the public. An essential strategy in accomplishing reinvention goals is the ability to periodically receive input and feedback from customers about the design and quality of the services they receive.

The NLM provides significant services directly to the public including health providers, researchers, universities, other federal agencies, state and local governments, and to others through a range of mechanisms, including publications, technical assistance, and web sites. These services are primarily focused on health and medical information dissemination activities. The purpose of this submission is to obtain OMB's generic approval to conduct satisfaction surveys of NLM's customers. The NLM will use the information provided by individuals and institutions to identify strengths and weaknesses in current services and to make improvements where feasible. The ability to periodically survey NLM's customers is essential to continually update and upgrade methods of providing high quality service.

Frequency of Response: Annually or biennially.

Affected Public: Individuals or households; businesses or other for profit; state or local governments; Federal agencies; non-profit institutions; small businesses or organizations.

Type of Respondents: Organizations, medical researchers, physicians and other health care providers, librarians, students, and the general public. Annual reporting burden is as follows:

Estimated Number of Respondents: 18,400.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours Per Response: .122.

Estimated Total Annual Burden Hours Requested: 2246.

The annualized cost to respondents is estimated at $30,256. There are no capital costs to report. There are no operating or maintenance costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity