The estimated number of recordkeepers, i.e., persons that separate mammalian and nonmammalian materials, is derived from inspections of firms handling animal protein intended for use in animal feed. The estimate of the time required for this recordkeeping requirement is based on agency communication with industry.

Dated: September 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25042 Filed 10–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0286]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 November 3, 2003.

ADDRESSES: The Office of Management and Budget (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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to the agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2002, there are an estimated 225 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions and some may have multiple submissions in a given year. The total number of annual responses is based on the average number of submissions received by FDA in FY 2000 through 2002. CDER estimates 2,494 annual responses that include the following submissions; 105 new drug applications; 1,557 chemistry supplements; 670 labeling supplements; and 162 efficacy supplements. CBER estimates 737 annual responses that include the following submissions; 11 biologics license applications; 640 manufacturing (chemistry) supplements; 72 labeling supplements; and 14 efficacy supplements. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of July 3, 2003 (68 FR 39954), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 3397	225	14.36	3,231	0.30	969
Total					969

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

Dated: September 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25043 Filed 10–2–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Children's Hospitals Graduate Medical Education Payment Program (CHGME PP) (OMB No. 0915–0247): Revision

The CHGME PP was enacted by Public Law 106–129 to provide Federal support for graduate medical education (GME) to freestanding children's hospitals. This legislation attempts to provide support for GME comparable to the level of Medicare GME support received by other, non-children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. Direct payments are designed to offset the expenses associated with operating approved graduate medical residency training programs and indirect payments are designed to compensate hospitals for expenses associated with the treatment of more severely ill patients and the additional costs relating to teaching residents in such programs.

Technical assistance workshops and consultation with applicant hospitals resulted in an opportunity for hospital representatives to raise issues and provide suggestions resulting in proposed revisions in the CHGME application forms and instructions.

Data is collected on the number of full-time equivalent residents in applicant children's hospitals' training programs to determine the amount of direct and indirect medical education payments to be distributed to participating children's hospitals. Indirect medical education payments will also be derived from a formula that requires the reporting of discharges, beds, and case mix index information from participating children's hospitals. Hospitals will be requested to submit such information in an annual application. Hospitals will also be requested to submit data on the number of full-time equivalent residents a second time during the Federal fiscal year to participate in the reconciliation payment process.

The estimated average annual reporting for this data collection is approximately 150 hours per hospital. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
HRSA 99–1	54	1	54	99.9	5,395
HRSA 99–1 (Reconciliation of FTE counts)	54	1	54	8	432
HRSA 99–2	54	1	54	14	756
HRSA 99–4	54	1	54	28	1,512
Total	54		54		8,095

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 16C–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 29, 2003.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 03–25092 Filed 10–2–03; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

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

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Dates and Times:

October 26, 2003, 5 p.m.–8 p.m.

October 27, 2003, 8:30 a.m.–5:30 p.m.

October 28, 2003, 8:30 a.m.–4 p.m.

Place: The Washington Terrace Hotel, 1515 Rhode Island Avenue, NW., Washington, DC 20005.

Status: The meeting will be open to the public.

Agenda: Agenda items will include, but not be limited to: Welcome; plenary session on cultural competency and diversity for the grant programs under the purview of the Committee with presentations by speakers representing the Department of Health and Human Services (DHHS), constituent groups, field experts and committee members. Meeting content will focus on how cultural competency and diversity relate to health status outcomes. The following topics will be addressed at the meeting: What are the Title VII grant programs doing in the areas of cultural competency and diversity and under what authority, if any? Why should there be a culturally competent and diverse workforce? and What are the policy issues