FDASIA). In addition, when pediatric studies under PREA are fully or partially waived by FDA because there is evidence that a drug would be ineffective or unsafe in a pediatric population or pediatric subpopulation, the safety concern or lack of efficacy must be reflected in the prescription drug labeling (section 505B(a)(4)(D) of the FD&C Act). All useful information on the use of drugs and biological products in the pediatric population should be consistently placed in the proper sections within prescription labeling so that the information is clear and accessible to health care providers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on incorporating pediatric information into human prescription drug and biological products labeling. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov*.

Dated: February 22, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–04625 Filed 2–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

ACTION: Notice.

SUMMARY: 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 the Office of Management and Budget (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, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: The Health Education Assistance Loan (HEAL) Program Regulations (OMB No. 0915–0108)—Extension

Abstract: The Health Education Assistance Loan (HEAL) Program has regulations that contain notification, reporting, and recordkeeping requirements to insure that the lenders and holders participating in the HEAL program follow sound management procedures in the administration of federally-insured student loans. While the regulatory requirements are approved under the OMB number referenced above, much of the burden associated with the regulations is cleared under separate OMB numbers for the HEAL forms and electronic submissions used to report required information. The table below provides the estimate of burden for the remaining regulations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

REPORTING REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response (min)	Total burden hours
13 Holders	4	52	12	10.40
0 Schools	0	0	0	0
Total Reporting				10.40

NOTIFICATION REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response (min)	Total burden hours
15,000 Borrowers	1	15,000	10	2,500.00
13 Holders	6,500	84,500	10	14,083.33
0 Schools	0	0	0	0
Total Notification				16,583.33

RECORDKEEPING REQUIREMENTS

Number of respondents	Number of transactions	Total transactions	Hours per response (min)	Total burden hours
13 Holders	2,600	33,800	14	7,886.67
0 Schools	0	0	0	0
Total Recordkeeping				7,886.67
Total Burden Hours				24,480.40

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Deadline: Comments on this Information Collection Request must be received within 60 days of this notice.

Dated: February 21, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–04723 Filed 2–27–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the following committee will convene its seventy-second meeting.

Name: National Advisory Committee on Rural Health and Human Services.

Dates and Time: April 3, 2013, 9:00 a.m.–5:00 p.m. April 4, 2013, 9:00 a.m.–5:00 p.m. April 5, 2013, 8:45 a.m.–11:15 a.m.

Place: Hospice & Palliative Care of Western Colorado, 3090 North 12th Street, Unit B, Grand Junction, CO 81506, Web site: *www.hospicewco.com.*

Phone: (970) 241–2212.

Status: The meeting will be open to the public.

Purpose: The National Advisory Committee on Rural Health and Human Services provides advice and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas.

Agenda: Wednesday morning, at 9:00 a.m., the meeting will be called to order by the Chairman of the Committee, the Honorable Ronnie Musgrove. The Committee will be examining hospice and palliative care for rural patients and efforts to ameliorate rural poverty. The day will conclude with a period of public comment at approximately 5:00 p.m.

Thursday morning, at approximately 9:00 a.m., the Committee will break into Subcommittees and depart for site visits to rural healthcare and human services providers in Colorado. One panel from the Health Subcommittee will visit Family Health West Hospital in Fruita, CO. Another panel from the Health Subcommittee will visit Plateau Valley Clinic in Collbran, CO. The Human Services Subcommittee will visit Montrose County Health and Human Services in Montrose, Colorado. The day will conclude at the Doubletree Hilton Grand Junction with a period of public comment at approximately 5:00 p.m.

The final session will be convened on Friday morning at 9:00 a.m. The Committee will summarize key findings from the meeting and develop a work plan for the next quarter and the following meeting. The meeting will adjourn at 11:15 a.m.

For Further Information Contact: Steve Hirsch, MSLS, Executive Secretary, National Advisory Committee on Rural Health and Human Services, Health Resources and Services Administration, Parklawn Building, Room 5A–05, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–0835, Fax (301) 443–2803.

Persons interested in attending any portion of the meeting should contact Nathan Nash at the Office of Rural Health Policy (ORHP) via telephone at (301) 443–0835 or by email at *nnash@hrsa.gov.* The Committee meeting agenda will be posted on ORHP's Web site *http://www.hrsa.gov/advisorycommittees/rural/.*

Dated: February 21, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–04652 Filed 2–27–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request: Request for Human Embryonic Stem Cell Line To Be Approved for Use in NIH Funded Research

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research (OER), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the