identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 part 801 have been approved under OMB control number 0910–0485; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910–0332; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073.

V. 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.*

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19686 Filed 8–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the American College of Gastroenterology, the American Gastroenterological Association, the Crohn's and Colitis Foundation of America, Inc., the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, and the Pediatric IBD Foundation, is announcing a 2-day public workshop entitled ''Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT II).'' Partners and stakeholders planning the workshop also include patients and representatives from the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. The purpose of this workshop is to provide a forum to consider issues related to endpoints that can support drug development in the following disease areas: Pediatric and adult inflammatory bowel diseases.

DATES: The public workshop will be held on October 21 and 22, 2013, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the National Institutes of Health, 31 Center Dr., Natcher Conference Center, Building 45, Bethesda, MD 20892–2178.

FOR FURTHER INFORMATION CONTACT: Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2302, FAX: 301–796–9905, email: *Kevin.Bugin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: This workshop will address endpoints for registration trials. Stakeholders, including industry sponsors, academia, patients, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in registration trials for products intended to treat adult and/or pediatric inflammatory bowel disease. The definition and measurement of treatment benefit in Crohn's disease registration trials, the role of existing and future clinical outcome assessments including development of patient reported outcome measures, timing of endpoint assessments, and dose-finding strategies will be discussed. In addition, there will be a followup to previous workshop discussions of endpoints and clinical trial design for ulcerative colitis registration trials. Strategies and methods to overcome the challenges of developing drugs in pediatric populations and facilitate the collection of dosing, safety, and efficacy information for drugs not currently approved for use in children will be discussed.

Participation in the Public Workshop:

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *http://www.great2.org* before October 1, 2013. For those without Internet access, please contact Kevin Bugin (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kevin Bugin (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–19684 Filed 8–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

Information Collection Request Title: Request for Benefits Form—Optional Collection of Additional Medical Records, Collection of Benefits Determination Documentation OMB No. 0915–0334—Revision

Abstract: This is a revision to the request for OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP). The CICP, within the Health Resources and Services Administration (HRSA), administers the compensation program authorized by the Public Readiness and Emergency Preparedness Act (PREP Act). The CICP provides compensation to eligible individuals (requesters) who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration, or to their estates and/or survivors. A declaration is issued by the Secretary of the Department of Health and Human Services (Secretary). The purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. In addition, the Secretary, through a declaration, may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

To determine whether a requester is eligible for CICP benefits (compensation) for the injury, the CICP must review the Request for Benefits Package, which includes the Request for Benefits Form and Authorization for Use or Disclosure of Health Information Form(s), as well as the injured countermeasure recipient's medical records and supporting documentation.

A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive medical benefits and/or benefits for lost employment income accrued prior to the injured countermeasure recipient's death. If death was the result of the administration or use of the countermeasure, certain survivor(s) of deceased eligible countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits. 42 CFR § 110.33. The death benefit is calculated using either the ''standard calculation'' or the ''alternative calculation.'' The ''standard calculation'' is based on the death benefit available under the Public Safety Officers' Benefits (PSOB) Program. 42 CFR 110.82(b). The ''alternative calculation'' is based on the deceased countermeasure recipient's income and is only available to the recipient's dependent(s) who is (are) younger than age 18. 42 CFR 110.82(c).

Approval is requested for the required continued information collection via the Request for Benefits Package, which has been updated to include all categories of potentially eligible requesters, including adult children, so that the CICP may continue to accept and process requests for benefits. The Request for Benefits Form and Instructions have been revised to remove the request for a Social Security number, update the CICP Web site address, and add a new category of eligible requesters, adult children. This new category was added because the CICP is generally required to use the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program. 42 CFR 110.11(b). This new category of survivors was added under the PSOB Program.

Approval is requested for new mechanisms of obtaining medical documentation and supporting documentation collection. During the eligibility review, the CICP would like to provide requesters with the opportunity to supplement their case files with additional medical records and supporting documentation before a final determination is made. The CICP would ask requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case.

Approval is requested for a benefits documentation package the CICP plans to send to requesters who may be eligible for compensation which includes certification forms and instructions outlining the documentation needed to determine the types and amounts of benefits. This documentation is required under 42 CFR 110.61–110.63 of the CICP's implementing regulations to enable the CICP to determine the types and amounts of benefits the requester may be eligible to receive.

Need and Proposed Use of the Information: The information collected from requesters to the CICP provides data and documentation that is needed for the Program to determine: (1) The requester's eligibility to receive benefits; and (2) if applicable, the type and amount of benefits that may be awarded.

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 ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Request for Benefits Form and Supporting Documentation	100	1	100	11	1100
Authorization for Use or Disclosure of Health Information Form	100	1	100	2	200
Additional Documentation and Certification	30	1	30	.75	22.5
Benefits Package and Supporting Documentation	30	1	30	.125	3.75

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Total	100				1326.25

Dated: August 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–19648 Filed 8–13–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 30-Day Proposed Information Collection: Application for Participation in the IHS Scholarship Program

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is submitting to the Office of Management and Budget (OMB) a request for a revision of an approved collection of information titled, ''Application for Participation in the IHS Scholarship Program (OMB Control Number 0917–0006),'' with an expiration date of August 31, 2013. This proposed information collection project was previously published in the **Federal Register** (78 FR 36197) on June 17, 2013, and allowed 60 days for public comment, as required by 3506(c)(2)(A). The IHS received no comments regarding this collection. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: ''Application for Participation in the IHS Scholarship Program (OMB Control Number 0917–0006).'' *Type of Information Collection Request:* Revision of the currently approved information collection, ''Application for Participation in the IHS Scholarship Program, (OMB Control No. 0917–0006).'' *Form Number(s):* IHS–856–3, IHS–856–5 through 856–19, IHS–856–21 through 856–24, IHS–817, and IHS–818 are retained for use by the IHS Scholarship Program (IHSSP) as part of this current Information Collection Request. Reporting forms are found on the IHS Web site at *www.ihs.gov/scholarship.* Form Numbers: IHS–856, IHS–856–2, IHS–856–4, IHS–856–20, IHS–815, and IHS–816 have been deleted from the previous Information Collection Request in an effort to comply with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). *Need and Use of Information Collection:* The IHS Scholarship Branch needs this information for program administration and uses the information to: solicit, process, and award IHS Pre-graduate, Preparatory, and/or Health Professions Scholarship recipients; monitor the academic performance of recipients; and to place recipients at payback sites. The IHS Scholarship Program streamlined the application process by converting the IHS–856 to an electronic tool and reduced the number of required supplemental application and reporting forms to minimize the time needed by applicants and recipients to complete the application process and provide required information after receiving a scholarship from the IHSSP. The IHSSP application is electronically available on the internet at the IHS Web site at: *http://www.ihs.gov/scholarship/apply_now.cfm.*

Affected Public: Individuals, not-for-profit institutions and State, local or Tribal Governments. *Type of Respondents:* Students pursuing health care professions.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Annual number of responses, Average burden hour per response, and Total annual burden hours.

Data collection instrument(s)	Number of respondents	Responses per respondent	Total annual response	Burden hour per response*	Annual burden hours
Faculty/Employer Evaluation (IHS–856–3)	1500	2	3000	0.42 (25 min)	1250
Delinquent Federal Debt (IHS–856–5)	1500	1	1500	0.13 (8 min)	200
Course Curriculum Verification (IHS–856–6)	1500	1	1500	0.70 (42 min)	1050
Verification of Acceptance or Decline of Award (IHS–856–7).	500	1	500	0.13 (8 min)	67
Recipient's Initial Program Progress Report (IHS–856–8)	1200	1	1200	0.13 (8 min)	160
Notification of Academic Problem (IHS–856–9)	50	1	50	0.13 (8 min)	7
Change of Status (IHS–856–10)	50	1	50	.045 (25 min)	21
Request for Approval of Deferment (IHS–856–11)	20	1	20	0.13 (8 min)	3
Preferred Placement (IHS–856–12)	150	1	150	0.50 (30 min)	75
Notice of Impending Graduation (IHS–856–13)	170	1	170	0.17 (10 min)	28
Notification of Deferment Program (IHS–856–14)	20	1	20	0.13 (8 min)	3
Placement Update (IHS–856–15)	170	1	170	0.18 (11 min)	31
Annual Status Report (IHS–856–16)	200	1	200	0.25 (15 min)	50
Extern Site Preference Request (IHS–856–17)	300	1	300	0.13 (8 min)	40
Request for Extern Travel Reimbursement (IHS–856–18)	150	1	150	0.10 (6 min)	15
Lost Stipend Payment (IHS–856–19)	50	1	50	0.13 (8 min)	7
Summer School Request (IHS–856–21)	100	1	100	0.10 (6 min)	10
Change of Name or Address (IHS–856–22)	20	1	20	0.13 (8 min)	3
Request for Credit Validation (IHS–856–23)	30	1	30	0.10 (6 min)	3
Faculty/Advisor Evaluation (IHS–856–24)	1500	2	3000	0.42 (25 min)	1250
Scholarship Program Agreement (IHS–817)	175	1	175	0.16 (10 min)	29