establishment registration within 5 days of such changes.

Section 607.30(a), in brief, sets forth the information required from owners or operators of establishments when updating their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs.

Section 607.31 requires that additional blood product listing information be provided upon FDA request.

Section 607.40, in brief, requires certain foreign blood product establishments to comply with the establishment registration and blood product listing information requirements discussed earlier in this document and to provide the name and address of the establishment and the name of the individual responsible for submitting the establishment registration and blood product listing information, as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities and is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply. Form FDA 2830 is used to collect this information.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments.

In the **Federal Register** of August 11, 2014 (79 FR 46838), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Form FDA 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial Registration	68	1	68	1	68
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Re-registration	2,615	1	2,615	0.5 (30 minutes)	1,308
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product Updating List.	166	1	166	0.25 (15 minutes)	42
Total						1,418

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

FDA estimates the burden of this collection of information based upon information obtained from FDA's Center for Biologics Evaluation and Research's database and FDA experience with the blood establishment registration and product listing requirements.

Dated: January 26, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01670 Filed 1–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–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, the North American Society for the Study of Celiac Disease, and the Pediatric Inflammatory Bowel Disease Foundation, is announcing a 2-day public workshop entitled ''Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT III).'' The purpose of this workshop is to provide a forum to consider issues related to selection of endpoints and clinical outcome measures appropriate for drug development in the following disease areas: Inflammatory bowel diseases and celiac disease.

DATES: The public workshop will be held on March 30 and 31, 2015, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Kelly Richards, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Rm. 5237, Silver Spring, MD 20993–0002, 240–402–4276, FAX: 301–796–9904, email: *GREAT@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: This workshop will address endpoints for registration trials in inflammatory bowel diseases and celiac disease. Stakeholders, including industry sponsors, academia, patients and FDA, will address challenging issues related to selection of endpoints and assessment methodologies in clinical trials intended to support approval of products for treatment of inflammatory bowel diseases and celiac disease. The first day of the workshop will discuss the assessment of efficacy in Crohn's disease trials, including the use of patient-reported outcome measures and endoscopic evaluation, as well as the role of registries and patient participation in inflammatory bowel disease drug development programs. The second day of the workshop will discuss the appropriate target population for pharmacological therapy in celiac disease, and the definition and measurement of a treatment benefit in celiac disease registration trials, including the role and timing of

assessment of histological and serological endpoints.

I. Participation in the Public Workshop

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.great3.org* before March 1, 2015. For those without Internet access, please contact Kelly Richards (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

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

II. 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. Fax requests to 301–827–9267.

Dated: January 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–01625 Filed 1–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 21, 2014, volume #79, page 69500 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 NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0941 or Email your request, including your address to *curriem@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH), 0925–0648, Expiration Date 1/31/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: There are no changes being requested for this submission. The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. This generic will provide information about the NIH Institutes and Centers customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information but it will not yield data that can be generalized to the overall population.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 49,358.

Estimated Annualized Burden Hours

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of espondents	Annual frequency per esponse	Hours per response	Total annual burden hours
Customer Satisfaction Surveys	1,000	1	30/60	500
In-Depth Interviews (IDIs) or Small Discussion Groups	1,000	1	90/60	1,500
Focus Groups	1,000	1	90/60	1,500
Usability and Pilot Testing	150,000	1	5/60	12,525
Conference/Training—Pre and Post Surveys	100,000	2	10/60	33,333