bottled or otherwise packaged beers subject to our jurisdiction. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions 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 collection of information in this guidance was approved under OMB control number 0910–0728.

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 guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Always access an FDA guidance document using FDA's Web site listed previously to find the most current version of the guidance.

V. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

1. TTB Ruling 2008–3, July 7, 2008, available at: *http://www.ttb.gov/rulings/2008–3.pdf.*

2. Memorandum of Understanding 225–88–2000 between FDA and Bureau of Alcohol, Tobacco and Firearms, available at: *http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm116370.htm.*

Dated: *December 17, 2014.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29988 Filed 12–22–14; 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; NIMH Data Repositories Data Submission Request; NIMH Data Repositories Data Access and Use Certification

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 October 7, 2014, page 60479 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 Institute of Mental Health (NIMH), National Institutes of Health, 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.

DATES: *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 or request more information on the proposed project contact: NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, OSPPC, NIMH, NIH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Rockville Pike, Bethesda, MD 20892, or call 301–443–4335 or Email your request, including your address to: *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection

NIMH Data Repositories (NDR) Data Submission Request—Revision 0925–0667; the NIMH Data Repositories Data Access and Use Certification—National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Mental Health (NIMH) Data Repositories are a group of Federal data repositories based on an informatics platform for human-subjects research domains related to mental health, initially established as the National Database for Autism Research (NDAR) to support autism-related research. In 2013, NIMH received approval from OMB for use of the NIMH Data Access Request and Use Certification (DUC) Form to meet the unique data access needs of all existing NIMH data repositories, which at the time consisted of NDAR, Pediatric MRI (PedsMRI), and the NIMH Clinical Research Datasets (NCRD)—OMB# 0925–0667 (Expiration: 09/30/2016). Now in 2014, two new databases have been added and integrated into the NDAR infrastructure, NDCT and RDoCdb. At this time, NIMH is seeking OMB approval to add an all-purpose NIMH Data Repositories Data Submission Request Form and to revise the all-purpose NIMH Data Repositories Data Access and Use Certification Form. As the data repositories have matured, and with the introduction of the new databases—namely NDCT and RDoCdb—the information being collected for data submission has become more complex, rendering an OMB-approved submission form a new necessity.

OMB approval is requested for three years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 221.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	A. Estimates annual burden hours			
	Number of respondents	Frequency of response	Average time per response (in hours)	Annual burden hour
NIMH Data Repositories Data Submission Request Form	40	1	95/60	63
NIMH Data Repositories Data Access and Use Certification Form	100	1	95/60	158

Dated: December 15, 2014.

Keisha Shropshire,

NIMH Project Clearance Officer, NIMH, NIH.

[FR Doc. 2014–30057 Filed 12–22–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The NIH/NCATS GRDR℠ Program: Global Rare Diseases Patient Registry Data Repository (GRDR)

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 July 30, 2014, page 44185 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 Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 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.

DATES: *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.

ADDRESSES: 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.

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: Dr. Yaffa Rubinstein, Director of Patient Resources for Clinical and Translational Research at the Office of Rare Diseases Research (ORDR), NCATS, NIH, Suite 1004, 6701 Democracy Boulevard, Bethesda, MD 20892–4874, or call non-toll-free number (301) 402–4338 or Email your request, including your address to: *yaffa.rubinstein@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Proposed Collection: NIH/NCATS GRDR℠ Program: Global Rare Diseases Patient Registry Data (GRDR), The National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: The NIH created the GRDR program *https://grdr.ncats.nih.gov* an informatics system and central data repository, housed at the NCATS/NIH Center to support and accelerate research in the cause, diagnosis, and treatment of rare diseases. The GRDR program collects a wide range of data types, including phenotypic and clinical information, as well as medical images, derived from individuals who participate in rare disease patient registries, regardless of the source of funding. The GRDR program provides the infrastructure to store, search across, retrieve, and analyze these varied types of data. This valuable information will help NIH understand and evaluate the use of repositories/datasets in the research community. The GRDR program will support: (1) Mapping data to standards; (2) increased visibility for participating registries; (3) opportunity for cross-disease research; (4) better and faster rare disease clinical research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 133.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Request for Open	Individuals	2000	1	1/60	33
Request for Controlled	Individuals	1000	1	5/60	83
Request to Submit	Individuals	100	1	10/60	17

Dated: December 9, 2014.

Pamela McInnes,

Deputy Director, NCATS, NIH.

[FR Doc. 2014–29640 Filed 12–22–14; 8:45 am]

BILLING CODE 4140–01–P