Meeting.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, October 12, 2017, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amanda Roache, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Strategic Programs, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring MD, 20993, 301–796–4548, email: *Amanda.Roache@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The ICH, formerly known as the International Conference on Harmonisation, was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness. In 2015 the ICH was reformed to make the ICH a true global initiative that expands beyond the previous ICH members. More involvement from regulators around the world is expected, as they will join their counterparts from Europe, Japan, the United States, Canada, and Switzerland as ICH regulatory members. The reforms build on a 25-year track record of successful delivery of harmonized guidelines for global pharmaceutical development, and their regulation. In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory Agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the ICH regions over the past two decades. The current ICH process and structure can be found at the following Web site: *http://www.ich.org.* (FDA has verified the Web site addresses as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Webinar Attendance and Participation

A. Registration

If you wish to attend the meeting, please register at the following Web site: *https://healthcanada-usfda_ich_consultation.eventbrite.ca.* For those attending online, a link will be provided upon registration. In person registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. If you need special accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the webinar.

B. Requests for Oral Presentations

Interested persons may present data, information, or views orally or in writing on issues pending at the public webinar. Public oral presentations will be scheduled between approximately 11:30 a.m. and 12 noon. Time allotted for oral presentations may be limited to 5 minutes. Those desiring to make oral presentations should notify Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) by October 12, 2017, and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names and addresses, telephone number, fax, and email of proposed participants; and an indication of the approximate time requested to make their presentation. The agenda for the public webinar will be made available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm574251.htm.*

Dated: September 29, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–21437 Filed 10–4–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–xxxx—New]

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, 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 no later than November 6, 2017.

ADDRESSES: Submit your comments, including the ICR 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation—OMB No. 0906–xxxx—New

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, an agency of HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). The SRTR contractor will establish a pilot living donor registry in which 14 transplant programs will register all potential living donors who provide informed consent to participate in the pilot registry. The SRTR's authority to collect information concerning potential living donors is set forth in the Organ Procurement and Transplantation Network final rule requiring Organ Procurement Organizations and transplant hospitals to submit to the SRTR, as appropriate, information regarding ''donors of organs'' and ''other information that the Secretary deems appropriate.'' 42 CFR 121.11(b)(2).

Need and Proposed Use of the Information: The transplant programs will submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the contractor. The SRTR contractor will maintain contact with registry participants and collect data on long-term health outcomes through surveys. The data collection will also include outcomes of evaluation including reasons for non-donation. The goal of the pilot registry is to develop data collection tools and survey instruments that can be used to expand the registry to include most, if not all, living donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living donors post donation will provide useful information to transplant programs in their future donor selection process and will aid potential living donors in their decision to pursue living donation.

Likely Respondents: Potential living donors, transplant programs, medical and scientific organizations, and public organizations.

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	Average number of responses per respondent	Total number of responses	Average burden per response (in hours)	Total burden hours
Potential Living Donor Registration form	14	55.43	776	1	776
Reasons Did not Donate Form (liver or kidney)	14	27.71	388	.50	194
Potential Living Donor Follow-up form	776	1	776	.50	388
Total	*804		1,940		1,358

*Number of respondents for potential living donor registration and reasons did not donate forms based on number of programs participating in the pilot registry. Number of respondents for potential living donor follow-up forms based on number of potential living donors evaluated at the 14 participating programs in 2015.

HRSA specifically 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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–21490 Filed 10–4–17; 8:45 am]

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