

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval.

To comply with the above requirement, ACL is publishing a notice of a new collection of information as set forth in this document. With respect to the following collection of information, ACL invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of ACL’s functions, including whether the information will have practical utility and/or help ACL illustrate the program’s return on investment; (2) the accuracy of ACL’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information

on respondents, including through the use of automated collection techniques when appropriate and other forms of information technology.

**Purpose**

The purpose of the Traumatic Brain Injury (TBI) State Partnership program is to increase access to rehabilitation and other services for individuals with traumatic brain injury. Under the Traumatic Brain Injury Reauthorization Act of 2014 (Pub. L. 113–196), the Traumatic Brain Injury State Partnership program transitioned from the Health Resources and Services Administration (HRSA) to the Administration for Community Living (ACL). Under this law, the Secretary, acting through ACL, was authorized to “make grants to States and American Indian consortia for the purpose of carrying out projects to improve access to rehabilitation and other services regarding traumatic brain injury.” ACL seeks to collect performance measure data from state grantees consistent with the TBI State Partnership program’s purpose and ACL’s mission to “Maximize the independence, well-being, and health of older adults, people with disabilities across the lifespan, and their families and caregivers.”

ACL seeks data on a semi-annual basis on the types of practices, protocols, and activities performed by each grantee, as well as the cost of each activity and the number and types of people they served. ACL also seeks

information about the number and types of individuals who receive TBI-related home and community based services. Finally, ACL seeks information regarding the involvement of people with TBI in advisory and program support roles.

The data collected will allow ACL to determine the extent to which the grant program is meeting its goals of expanding and improving services, generating sustainable funding streams, and enriching service systems to better serve individuals with TBI and their families. The data will also help ACL develop and expand baseline information around the nature and scope of the incidence of TBI. Additionally, this data collection will help ACL illustrate the return on investment of the TBI funds in terms of system change (*i.e.*, changes in policies and practices and the development of networks). By matching the project dollars spent against measurable improvements in state systems for delivering services and supports to people living with TBI, ACL will have a strong indicator of the effect of the TBI program on the quality of services which ultimately impact the lives of people across the country living with TBI. The proposed data collection forms may be found on the ACL Web site for review at: <https://www.acl.gov/about-acl/public-input>.

*Estimated Program Burden:* The annual reporting burden estimates are shown below.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
States .....	State Performance Report .....	* 45	2	16	1,440

\* This is the highest number of awards anticipated, but it is possible that there will be less. If less than 45 grants are awarded, the total burden hours will be adjusted proportionally.

Dated: November 7, 2017.

**Mary Lazare,**

*Principal Deputy Administrator.*

[FR Doc. 2017–24525 Filed 11–9–17; 8:45 am]

**BILLING CODE 4154–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–D–5138]

**S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals; International Council for Harmonisation; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft

guidance entitled “S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.” The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance replaces the existing guidance entitled “S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.” The draft guidance is intended to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 12, 2018.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff Office, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2017-D-5138 for "S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

<https://www.regulations.gov> or at the Dockets Management Staff Office 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 Office. 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, September 18, 2015, 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.

Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillendale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be

obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

*Regarding the guidance:* Abigail Jacobs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6474, Silver Spring, MD 20993-0002, 301-796-0174; or Martin (Dave) Green, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3270, Silver Spring, MD 20993-0002, 301-796-2640. *Regarding the ICH:* Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993-0002, 301-796-4548.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals." In recent years, regulatory authorities and industry associations have participated in many important initiatives to promote international harmonization of regulatory requirements. FDA has participated in several 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 reduce differences in technical requirements for drug 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. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER and CBER, FDA; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and

Swissmedic. Any party eligible to become a member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers.

In August 2017, the ICH Assembly endorsed the draft guidance titled “S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals” and agreed that the guidance should be made available for public comment. The draft guidance is the product of the S5(R3) Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the S5(R3) Safety Expert Working Group.

The draft guidance replaces the existing guidance entitled “S5(R2) Detection of Toxicity to Reproduction for Human Pharmaceuticals.” The guidance has undergone major revisions to align with other ICH guidances, elaborate on concepts to consider when designing studies, and identify potential circumstances in which a risk assessment can be made based on preliminary studies. It also clarifies the qualification and potential use of alternative assays.

To support using alternative assays, compounds that are either positive or negative in their ability to induce embryoletality or malformations are used in the process of qualifying the assays. Although a number of compounds have been identified in the draft guidance’s Annex, section 11.3.4, Tables 9–6 and 9–7, with the type of information for the compounds, the list is not complete; therefore, FDA is requesting data in the form of public comments to the docket for additional positive and negative reference compounds for potential inclusion into the list. These compounds can be either pharmaceuticals or non-pharmaceuticals and should be commercially available. For additional guidance, please refer to Endnote 3 in the S5(R3) guidance. This is not a request for data for the compounds already listed in Table 9–6, nor is this a request for examples of assays that could be used.

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 current thinking of FDA

on “S5(R3) Detection of Toxicity to Reproduction for Human Pharmaceuticals.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.regulations.gov>, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

Dated: November 2, 2017.

**Anna K. Abram,**

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

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### **Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration, OMB No. 0915–0212—Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than January 12, 2018.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance

Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** 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](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (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:* Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration OMB No. 0915–0212—Extension.

*Abstract:* In response to Executive Order 12862, HRSA is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting continued approval for a generic clearance from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class evaluation forms completed by providers who receive training from HRSA grantees to measure satisfaction with the training experience. HRSA will use the results of these surveys to plan and redirect resources and efforts as needed to improve services and processes.

HRSA may also use focus groups to gain partner input into the design of mail and telephone surveys. Focus groups, in-class evaluation forms, mail surveys, and telephone surveys are expected to be the preferred data collection methods.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If this request receives continued approval, information on each individual partner survey will not be published in the **Federal Register**.

*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