ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is establishing a public docket to collect comments related to a proposed Study Data Reviewer's Guide (SDRG) template. As part of FDA's ongoing collaboration with the Pharmaceutical Users Software Exchange (PhUSE), an independent, non-profit consortium addressing computational science issues, a PhUSE working group developed the PhUSE SRDG template. The purpose of this review is to evaluate the template and determine whether FDA will recommend its use either as is, or in a modified form, for regulatory submissions of study data. FDA is seeking public comment on the use of the PhUSE SDRG template for regulatory submissions.

DATES: Although you can comment on the PhUSE SRDG template at any time, to ensure that the Agency considers your comments in this review, please submit either electronic or written comments by September 21, 2015.

ADDRESSES: Submit written requests for single copies of the PhUSE SDRG template to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Crystal Allard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 1518, Silver Spring, MD 20993–0002, 301–796–8856, *crystal.allard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is a participating member of PhUSE, an independent, non-profit consortium of academic, regulatory, non-profit, and private sector entities. PhUSE provides a global platform for the discussion of topics encompassing the work of biostatisticians, data managers, statistical programmers, and e-clinical information technology professionals, with the mission of providing an open, transparent, and collaborative forum to address computational science issues. As part of this collaboration, PhUSE working groups develop and periodically publish proposals for enhancing the review and analysis of human and animal study data submitted to regulatory agencies. You can learn more about PhUSE working groups at *http://www.phuse.eu/cs-working-groups.aspx.*

In December 2014, FDA published the Study Data Technical Conformance Guide (the ''Guide,'' available at *http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm*), which contains technical recommendations to sponsors for the submission of animal and human study data and related information in a standardized electronic format. In section 2.2 of the Guide, FDA recommends that each submitted study contain a Study Data Reviewer's Guide containing any special considerations or directions that may facilitate review of the study data. FDA notes in the Guide that the PhUSE SDRG template is an example of how to create an SDRG, but does not specifically recommend its use.

FDA now intends to review the PhUSE SDRG template, a deliverable of the working group effort described above, with the potential result that FDA could recommend the use of the template in its current form, or in a modified form, for use in the regulatory submission of study data in conformance with the Guide. FDA invites public comment on all matters regarding the use of the PhUSE SDRG template. Interested persons may submit either electronic comments 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.*

II. Electronic Access

The PhUSE SDRG template is available online at *http://www.phusewiki.org/wiki/index.php?title=Study_Data_Reviewer's_Guide.*

Dated: July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18027 Filed 7–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0781]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 08, 2015, the Agency submitted a proposed collection of information entitled, ''Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0428. The approval expires on July 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: July 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18042 Filed 7–22–15; 8:45 am]

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