Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0112, GSA Form 3040, State Agency Monthly Donation Report of Surplus Personal Property, in all correspondence.

Dated: August 22, 2018.

David A. Shive,

Chief Information Officer.

[FR Doc. 2018–18788 Filed 8–29–18; 8:45 am]

BILLING CODE 6820–34–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0014; Docket No. 2018–0001; Sequence No. 7]

Information Collection; Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123

AGENCY: Federal Acquisition Service, General Services Administration (GSA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding the Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123.

DATES: Submit comments on or before: October 29, 2018.

ADDRESSES: Submit comments identified by Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123,'' on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Ms. Mandell/IC 3090–0014.

Instructions: Please submit comments only and cite Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Willett, Property Disposal Specialist, GSA Office of Personal Property Management, at telephone 703–605–2873 or via email to *christopher.willett@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. Purpose

The Transfer Order—Surplus Personal Property and Continuation Sheet, Standard form (SF) 123, is used by a State Agency for Surplus Property (SASP) to donate Federal surplus personal property to public agencies, nonprofit educational or public health activities, programs for the elderly, service educational activities, and public airports. The SF 123 serves as the transfer instrument and includes item descriptions, transportation instructions, nondiscrimination assurances, and approval signatures.

B. Annual Reporting Burden

Respondents (electronic): 30,890.
Respondents (manual): 312.
Total Number of Respondents: 31,202.
Total Hours per Response (electronic at .017 Hours per Response): 525.13.
Total Hours per Response (manual at .13 Hours per Response): 40.56.
Total Burden Hours: 565.69.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC, 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, in all correspondence.

Dated: August 22, 2018.

David A. Shive,

Chief Information Officer.

[FR Doc. 2018–18790 Filed 8–29–18; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1041]

Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry; Availability; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the comment period for the notice of availability for ''Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry,'' published in the **Federal Register** of June 1, 2018. The Agency has received a request for an extension of the comment period for the draft guidance.

DATES: FDA is reopening the comment period on the notice of availability published June 1, 2018 (83 FR 25468). Submit either electronic or written comments on the draft guidance by September 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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, 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–2018–D–1041 for ''Development of a Shared System Risk Evaluation and Mitigation Strategy; Draft Guidance for Industry.'' 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 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, 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–5162, email: *Lubna.Merchant@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 1, 2018 (83 FR 25468), FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''Development of a Shared System Risk Evaluation and Mitigation Strategy.''

The Agency has received a request for an extension of the comment period for the draft guidance. FDA has considered the request and is reopening the comment period for the draft guidance until September 13, 2018. The Agency believes that a 14-day reopening of the comment period allows adequate time for interested persons to submit comments to ensure that the Agency can consider the comments on this draft guidance before it begins work on the final version of the guidance.

II. Electronic Access

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

Dated: August 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18775 Filed 8–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0049]

Complex Innovative Designs Pilot Meeting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The sixth iteration of the Prescription Drug User Fee Act (PDUFA VI), incorporated as part of the FDA Reauthorization Act of 2017 (FDARA), highlights the goal of facilitating and advancing the use of complex adaptive, Bayesian, and other novel clinical trial designs. The Food and Drug Administration (FDA or Agency) is announcing a pilot meeting program that affords sponsors who are selected the opportunity to meet with Agency staff to discuss the use of complex innovative trial design (CID) approaches in medical product development. Meetings under the pilot program will be conducted by FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) during fiscal years 2018 to 2022. This pilot meeting program fulfills FDA's commitment under PDUFA VI. For each sponsor whose meeting request is granted as part of the pilot, FDA will grant two meetings between the sponsor and CDER or CBER that will provide an opportunity for medical product developers and FDA to discuss regulatory approaches for CID. To promote innovation in this area, trial designs developed through the pilot meeting program may be presented by FDA (*e.g.,* in a guidance or public workshop) as case studies, including