notices, CBER is requesting that those firms that have previously applied and are still interested in participating reaffirm their interest. CBER is also requesting that new interested parties apply.

II. RSVP

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the facility, small groups of CBER staff may observe operations of biologics establishments, including for example, blood and tissue establishments. The visits may include the following: (1) Packaging facilities, (2) quality control and pathology/toxicology laboratories, and (3) regulatory affairs operations. These visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but are meant to improve mutual understanding and to provide an avenue for open dialogue between the biologics industry and CBER.

B. Site Selection

CBER will be responsible for all travel expenses associated with the site visits. Therefore, selection of potential facilities will be based on the coordination of CBER's priorities for staff training as well as the limited available resources for this program. In addition to logistical and other resource factors to consider, a key element of site selection is a successful compliance record with FDA or another Agency with which we have a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract to the applicant, the other firm also needs to agree to participate in the program, as well as have a satisfactory compliance history. If you are a firm with multiple sites, please submit no more than three specific locations for consideration.

III. Requests for Participation

Identify requests for participation with the docket number found in brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01780 Filed 2–1–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0908]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' 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 September 22, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees'' 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 0910–0581. The approval expires on December 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: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01781 Filed 2–1–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0609]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' 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 September 21, 2015, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification'' 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 0910–0806. The approval expires on December 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: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01784 Filed 2–1–16; 8:45 am]

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