

Workshop objectives will include discussion and identification of promising innovations that could facilitate successful trials in OA, new approaches to recruitment for clinical trials, feasible and clinically meaningful trial endpoints, and approaches for reducing the time and cost of OA trials while maximizing the likelihood of success.

Registration: There is no fee to attend the workshop, but attendees must register in advance. Space is very limited. Persons interested in attending this workshop may request to register by sending their resume and inquiry to AFScience@arthritis.org. The registration deadline is February 2, 2016.

II. Accommodations

An online registration link and a meeting code will be provided through the registration process giving participants a reduced group rate for hotel accommodations, not including applicable taxes. No additional reservations are required. Industry and government attendees are responsible for the cost of their own accommodations. If you need special accommodations due to a disability, please contact Becky Bosworth at bbosworth@arthritis.org at least 7 days in advance.

III. Transcripts

No transcripts will be available from the event, however, the event will be video taped for the purposes of the Arthritis Foundation. Speaker presentation materials, if permitted by the presenter, will be available on the Arthritis Foundation Web site following the workshop.

Dated: January 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0145]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities” 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 November 30, 2015, the Agency submitted a proposed collection of information entitled “Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities” 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 0910-0726. The approval expires on January 31, 2019. 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0275]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA’s) Center for Biologics Evaluation and Research (CBER) is announcing an invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give CBER staff a better understanding of the biologics industry,

including its challenges and operations. The purpose of this document is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit either an electronic or written request for participation in this program by March 3, 2016. The request should include a description of your facility relative to products regulated by CBER. Please specify the physical address(es) of the site(s) you are offering.

ADDRESSES: If your biologics facility is interested in offering a site visit, submit either an electronic request to <http://www.regulations.gov> or a written request to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. If you previously responded to earlier requests to participate in this program and you continue to be interested in participating, please renew your request through a submission to the Division of Dockets Management.

FOR FURTHER INFORMATION CONTACT: Cynthia Whitmarsh, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993-0002, 240-402-8010, FAX: 301-595-1243, email: Industry.Biologics@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and availability of biological products to patients. To support this primary goal, CBER has initiated various training and development programs, including programs to further enhance performance of its compliance staff, regulatory review staff, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff with a better understanding of the biologics industry and its operations. Further, CBER seeks to enhance: (1) Its understanding of current industry practices and regulatory impacts and needs and (2) communication between CBER staff and industry. CBER initiated its RSVP in 2005. Through these annual