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. 2016–01781 Filed 2–1–16; 8:45 am]
BILLING CODE 4164–01–P