DPM

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0408]

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 the initiation of a Regulatory Site Visit Training Program. This program is intended to give CBER's regulatory review staff, compliance staff, and other relevant staff an opportunity to visit biologics facilities. The visit is intended to provide first hand experience to CBER staff and to give a better understanding of the biologics industry, including its challenges and its operations. The purpose of this notice is to invite biologics companies interested in participating in this program to contact CBER for more information.

DATES: Submit a written or electronic requests for participation in this program by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, you should submit a request to participate in this program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Lonnie Warren-Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *cbertrainingsuggestions@cber.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates biological products including blood and blood products, vaccines, and cellular and gene therapies. CBER is committed to advancing the public health through innovative regulations that help ensure the safety, effectiveness, and timely delivery to patients of biological products. CBER has initiated various training and development programs to promote high performance of its regulatory review staff, compliance staff, and other relevant CBER staff. CBER seeks to continuously enhance and update review efficiency and quality as well as the quality of its regulatory efforts and interactions. CBER is initiating the Regulatory Site Visit Training Program to provide CBER staff the opportunity to visit biologics facilities to observe first-hand the industry's biologic development and manufacturing processes and thereby obtain better understanding of the biologics industry and its operations.

Further, this program is intended to improve CBER's understanding of current practices, regulatory impacts and needs, and improve communication between CBER staff and industry. The first phase of the program will focus on blood, plasma, and fractionation industries including transfusion centers, although other industries may be considered including vaccines, cellular and gene therapy, and tissues.

II. The Regulatory Site Visit Training Program

A. Regulatory Site Visits

In this program, over a period of time to be agreed upon with the biologics facility, small groups (five or less) of CBER staff may observe operations of biologics manufacturing, packaging, pathology/toxicology laboratory testing, and 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 enforcement function, but are meant to improve mutual understanding and to provide an avenue for open dialog between the biologics industry and CBER.

B. Site Selection

All travel expenses associated with the site visits will be the responsibility of CBER. Therefore, selection of potential biologics facilities will be based on

the coordination of CBER's priorities for staff training and the limited available resources for this program.

Dated: 9/16/04
September 16, 2004.

Jeffrey Shuren,
Assistant ~~Associate~~ Commissioner for Policy.

bb 9-17-04

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