

Dated: February 1, 2010.

Elaine L. Baker,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

**[Docket No. FDA-2008-N-0045] (formerly
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 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 notice is to invite biologics facilities to contact CBER for more information if they are interested in participating in this program.

DATES: Submit a written or electronic request for participation in this program by March 11, 2010. 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, you should submit a request to participate in the 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.regulations.gov>. 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: Lonnie W. Henderson, 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: matt@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, and through these annual notices, is requesting those firms that have previously applied and are still interested in participating, to reaffirm their interest, as well as requesting new interested parties to 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 packaging facilities, quality control and pathology/toxicology laboratories, 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 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

All travel expenses associated with the site visits will be the responsibility of CBER. 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 also 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.

III. Requests for Participation

Requests are to be identified with the docket number found in the brackets in the heading of this document. Received requests are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-2758 Filed 2-8-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-3308-EM; Docket ID FEMA-2010-0002]

Oklahoma; Emergency and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of an emergency for the State of Oklahoma (FEMA-3308-EM), dated January 30, 2010, and related determinations.

DATES: *Effective Date:* January 30, 2010.

FOR FURTHER INFORMATION CONTACT: Peggy Miller, Disaster Assistance Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-3886.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated January 30, 2010, the President issued an emergency declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5207 (the Stafford Act), as follows:

I have determined that the emergency conditions in certain areas of the State of Oklahoma resulting from a severe winter storm beginning on January 28, 2010, and continuing, are of sufficient severity and magnitude to warrant an emergency declaration under the Robert T. Stafford

Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* ("the Stafford Act"). Therefore, I declare that such an emergency exists in the State of Oklahoma.

You are authorized to provide appropriate assistance for required emergency measures, authorized under Title V of the Stafford Act, to save lives and to protect property and public health and safety, and to lessen or avert the threat of a catastrophe in the designated areas. Specifically, you are authorized to provide assistance for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program. This assistance excludes regular time costs for subgrantees' regular employees.

Consistent with the requirement that Federal assistance is supplemental, any Federal funds provided under the Stafford Act for Public Assistance will be limited to 75 percent of the total eligible costs. In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal emergency assistance and administrative expenses.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, Department of Homeland Security, under Executive Order 12148, as amended, Gregory W. Eaton, of FEMA is appointed to act as the Federal Coordinating Officer for this declared emergency.

The following areas of the State of Oklahoma have been designated as adversely affected by this declared emergency:

All 77 counties of the State of Oklahoma for emergency protective measures (Category B), limited to direct Federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2010-2798 Filed 2-8-10; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection for Energy and Mineral Development Program Grants; Comment Request

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of Submission to the Office of Management and Budget.

SUMMARY: The Bureau of Indian Affairs (BIA) is submitting the new information collection on the Energy and Mineral Development Program Grants for review and approval as required by the Paperwork Reduction Act. The Office of Management and Budget (OMB) will assign a Control Number.

DATES: Submit comments on or before March 11, 2010.

ADDRESSES: You may submit comments on the information collection to the Desk Officer for Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395-5806 or you may send an e-mail to: OIRA_DOCKET@omb.eop.gov. Please send a copy of your comments to Darryl Francois, Department of the Interior, Office of Indian Energy and Economic Development, Room 20, South Interior Building, 1951 Constitution Avenue, NW., Washington, DC 20245, fax (202) 208-4564; e-mail: Darryl.Francois@bia.gov.

FOR FURTHER INFORMATION CONTACT: You may request further information or obtain copies of the information collection request submission from Darryl Francois, Department of the Interior, Office of Indian Energy and Economic Development. Telephone (202) 219-0740.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Energy Policy Act of 2005 authorizes the Secretary of the Interior to provide grants to Indian tribes for energy development. *See* 25 U.S.C. 3502. The Office of Indian Energy and Economic Development (IEED) administers and manages the Energy and Minerals Development Program (EMDP). Congress appropriates funds to EMDP on a year-to-year basis. When funding is available, IEED may solicit proposals for energy and mineral development projects from Indian tribes whose lands are held in trust or restricted fee by the Federal government. Tribes may use the contracting mechanism established by the Indian Self-Determination Act or may receive the grant money through adjustments to their funding from the

Office of Self-Governance. *See* 25 U.S.C. 450 *et seq.* The projects may be in the areas of exploration, assessment, development, feasibility, or market studies. Indian tribes that would like to apply for an EMDP grant must submit an application that includes certain information, and must assist IEED by providing information in support of any National Environmental Policy Act (NEPA) analyses. A complete application must contain the following elements.

- A current, signed tribal resolution that: (1) Authorizes the energy and mineral development project for the appropriate fiscal year; (2) describes the commodity or commodities to be studied; (3) states that the tribe is willing to consider developing any potential energy or mineral resources discovered; (4) describes how the tribe prefers to have the energy or mineral program conducted (*i.e.*, through the sole utilization of IEED in-house professional staff, in conjunction with professional tribal staff, through private contractors, or through other appropriate means); and (5) states that the tribe will consider public release of information obtained from the energy and mineral development study upon request from IEED.
 - A proposal describing the planned activities and deliverable products that will be accomplished within the fiscal year for which funding is requested, including:
 - Overview, including the elements of the proposed study, reasons why the proposed study is needed, total requested funding, responsible parties for technical extraction and administration, and tribal point of contact for the project;
 - Technical summary of the project, including whether the request will begin a new study or continue a study and the duration of the study, a description of any known energy and/or mineral deposit, reference to any existing mineral exploration information, and a description of any environmental or cultural sensitive areas;
 - Project objective, goals and scope of work;
 - Deliverable products, such as technical data and maps; and
 - Resumes of key personnel.
 - A detailed budget estimate, including contracted personnel costs, travel estimates, data collection and analysis costs, and other expenses.
- The IEED requires this information to ensure that it provides funding only to