

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Interstate Shellfish Dealers Certificate (OMB Control Number 0910-0021)—Extension**

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors.

Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate." FDA uses this information to publish the "Interstate Certified Shellfish Shippers List," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3038	39	62	2,418	.10	242

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: April 3, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-5222 Filed 4-10-06; 8:45 am]

BILLING CODE 4160-01-S

**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 reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER's 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 staff a better understanding of the biologics industry, including its challenges and operations. This notice invites biologics facilities interested in participating in this program to contact CBER for more information.

**DATES:** Submit written or electronic requests for participation in this program by May 11, 2006.

**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 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.fda.gov/dockets/ecomments>.

If your biologics facility has previously responded to the notice announced in the **Federal Register** of September 23, 2004 (69 FR 57033), and you wish to continue to be considered for this year's program, you should notify CBER of your continued interest

by sending an e-mail to [matt@cber.fda.hhs.gov](mailto:matt@cber.fda.hhs.gov).

**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: [matt@cber.fda.hhs.gov](mailto:matt@cber.fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

CBER regulates 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 timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its regulatory review, compliance, 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

staff with a better understanding of the biologics industry and its operations.

CBER initiated its RSVP in 2005. This program is intended to improve CBER's understanding of current practices, regulatory impacts and needs, and communication between CBER staff and industry. CBER is reannouncing the invitation for participation in its RSVP, and is requesting those firms who previously applied and are still interested in participating to reaffirm their interest, as well as encouraging 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 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 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 CBER or another agency for which we have a memorandum of understanding.

Dated: March 31, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-5221 Filed 4-10-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2000D-1341]

#### **Draft Guidance for Industry: Center for Biologics and Evaluation Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier; Withdrawal of Guidance**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on July 11, 2001.

**DATES:** April 11, 2006.

#### **FOR FURTHER INFORMATION CONTACT:**

Pamela Pope, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of July 11, 2001 (66 FR 36287), FDA announced the availability of a draft guidance entitled "Guidance for Industry: CBER Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained from an Outside Supplier." This draft guidance described a pilot program in which biologics manufacturers could self-certify conformance to licensing criteria prescribed by FDA. This action was intended to reduce unnecessary burdens for industry without diminishing public health protection.

The draft guidance is being withdrawn because FDA has determined that there is a lack of industry interest in pursuing the pilot licensing program outlined in the draft guidance.

Dated: March 31, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-5220 Filed 4-10-06; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **National Eye Institute; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Eye Institute Special Emphasis Panel, NEI P30/R24 Review Meeting.

*Date:* April 20, 2006.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Sofitel Lafayette Square, 806 15th Street, NW., Washington, DC 20005.

*Contact Person:* Samuel Rawlings, PhD, Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, 5635 Fishers Lane, Suite 1300, MSC 9300, Bethesda, MD 20892-9300, 301-451-2020.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: April 3, 2006.

**David Clary,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-3415 Filed 4-10-06; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### **National Toxicology Program (Ntp); Office of Chemical Nomination and Selection; Announcement of and Request for Public Comment on Toxicological Study Nominations to the NTP**

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health.

**ACTION:** Notice; request for comments and additional information.

**SUMMARY:** The NTP continuously solicits and accepts nominations for toxicological studies to be undertaken by the program. Nominations of substances of potential human health concern are received from federal agencies, the public, and other interested parties. These nominations are subject to several levels of review before selections for testing are made and toxicological studies are designed and implemented. This notice (1) provides brief background information