

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Draft Guidance for Industry: Center for Biologics and Evaluation Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained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SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on July 11, 2001.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]

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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]

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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