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Draft Guidance for Industry: Center for Biologics and Evaluation Pilot Licensing Program for Immunization of Source Plasma Donors Using Immunogen Red Blood Cells Obtained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SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance that was issued on July 11, 2001.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

and study recommendations regarding 10 nominations for study by the NTP (Table 1), (2) solicits public comment on the nominations and study recommendations, and (3) requests the submission of additional relevant information for consideration by the NTP in its continued review of these nominations. An electronic copy of this announcement, supporting documents for each nomination, and further information on the NTP and the NTP Study Nomination and Review Process can be accessed through the NTP Web site (*http://ntp.niehs.nih.gov/;* select ''Nominations to the Testing Program'').

DATES: Comments or information should be submitted by May 10, 2006.

ADDRESSES: Correspondence should be addressed to Dr. Scott A. Masten, Director, Office of Chemical Nomination and Selection, NIEHS/NTP, 111 T.W. Alexander Drive, P. O. Box 12233, Research Triangle Park, North Carolina 27709; telephone: 919–541–5710; FAX: 919–541–3647; e-mail: *masten@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background Information

The NTP actively seeks to identify and select for study chemicals and other substances for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal open nomination and selection process. Nominations can be submitted to the NTP at *http://ntp.niehs.nih.gov/* select ''Nominations to the Testing Program'' or by contacting Dr. Scott Masten (see **ADDRESSES** above). Substances considered appropriate for study generally fall into two broad yet overlapping categories: (1) Substances judged to have high concern as possible public health hazards based on the extent of human exposure and/or suspicion of toxicity and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or for evaluating dose-response relationships. Nominations are also solicited for studies that permit the testing of hypotheses to enhance the predictive ability of future NTP studies, address mechanisms of toxicity, or fill significant gaps in the knowledge of the toxicity of classes of chemical, biological, or physical agents.

Study nominations may entail the evaluation of a variety of health-related effects including, but not limited to, reproductive and developmental toxicity, genetic toxicity, immunotoxicity, neurotoxicity, metabolism and disposition, and carcinogenicity in appropriate experimental models. In reviewing and selecting nominations for study, the NTP also considers legislative mandates that require responsible private sector organizations to evaluate their products for health and environmental effects. The possible human health consequences of anticipated or known human exposure, however, remain the over-riding factor in the NTP's decision to study a particular substance.

Nominations undergo a multi-step, formal process of review. Briefly, during the entire nomination review and selection process, the NTP works with staff at other federal agencies and interested parties to supplement information about nominated substances and to ensure that regulatory and public health needs are addressed. The nomination review and selection process is accomplished through the participation of representatives from the NIEHS, other federal agencies represented on the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the NTP Board of Scientific Counselors (BSC)—an external scientific advisory body, the NTP Executive Committee—the NTP federal interagency policy body, and the public. Preliminary study recommendations for each nomination are developed and refined by the nominator, NTP staff, and the ICCEC. Preliminary study recommendation for the nominations may be refined as the formal review process continues. NTP also considers recommendations from the BSC and the NTP Executive Committee, public comments received on the nominations, and other available information in selecting candidate substances for study. The NTP initiates appropriate toxicology and carcinogenicity studies as time and resources permit.

The nomination review and selection process is described in further detail on the NTP Web site (*http://ntp.niehs.nih.gov/;* select ''Nominations to the Testing Program'').

Request for Comments and Additional Information

The NTP invites interested parties to submit written comments or supplementary information on the nominated substances and study recommendations that appear in Table 1. The NTP welcomes toxicology and carcinogenesis study information from completed, ongoing, or anticipated studies, as well as information on current U.S. production levels, use or consumption patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. The NTP is interested in identifying appropriate animal and non-animal experimental models for mechanistic-based research, including genetically modified rodents and higher-throughput in vitro test methods, and as such, solicits comments regarding the use of specific in vivo and in vitro experimental approaches to address questions relevant to the nominated substances and issues under consideration. The BSC will discuss the nominations listed in Table 1 at a public meeting on June 13, 2006. A separate **Federal Register** notice will be published in the future about this meeting. Comments or additional information may be submitted at any time; however, to ensure adequate time for consideration prior to the June 13, 2006 BSC meeting, comments should be submitted by May 10, 2006. The NTP will not respond to submitted comments; however, all information received will be become part of the official record that the NTP considers in its ongoing review of these nominations. Persons submitting comments should include their name, affiliation, mailing address, phone, fax, e-mail address, and sponsoring organization (if any) with the submission. Written submissions will be made publicly available electronically on the NTP website as they are received (*http://ntp.niehs.nih.gov/* select ''Nominations to the Testing Program'').

Background Information on the NTP Office of Chemical Nomination and Selection

The NTP Office of Chemical Nomination and Selection (OCNS) manages the solicitation, receipt, and review of NTP toxicology study nominations. The OCNS conducts an initial review of each study nomination received to determine whether the substance or issue has been adequately studied or has been previously considered by the NTP. For nominations not eliminated from consideration or deferred at this stage, the OCNS initiates a formal review process, as described above. The OCNS also ensures adequate background information is available to support the review for each nomination and corresponds with interested parties regarding the status of NTP study nominations. For further information on the OCNS visit the NTP Web site (*http://ntp.niehs.nih.gov* select ''Nominations to the Testing Program'') or contact Dr. Masten (see **ADDRESSES** above).

Dated: March 28, 2006.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences and National Toxicology Program.

TABLE 1.—STUDY RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES

Substance [CAS No.]	Nominated by [1]	Nomination Rationale	Study Recommendations [2]
Arbutin 497–76–7]	NIEHS	Consumer exposure through food, cosmetics, and dietary supplements; lack of adequate toxicological data; suspicion of toxicity based on chemical structure.	—In vitro and in vivo metabolism and disposition studies. —In vitro and in vivo genotoxicity studies. —Emphasis on understanding gastrointestinal metabolism and disposition, identifying experimental animal model representative of humans, and development of appropriate biomarkers.
tert-Butylacrylamide [107–58–4]	NCI	High production volume (HPV); potential worker and consumer exposures; lack of adequate toxicological data; suspicion of toxicity based on chemical structure.	—Metabolism and disposition studies. —Subchronic toxicity studies. —Mammalian genotoxicity studies. —Coordinate studies with voluntary data development activities of the Extended HPV (EHPV) Program.
Ceric oxide [1306–38–3]	NIEHS	Widespread industrial use and potential for increasing exposure; demonstrated pulmonary toxicity; lack of toxicity data for nanoscale form. —Toxicological characterization including chemical disposition and toxicokinetics. —Comparative inhalation toxicity studies of microscale and nanoscale forms. —Dermal penetration studies.	
Diazonaphthoquinone derivatives Sodium 1,2-naphthoquinone-2-diazide-5-sulfonate [2657–00–3] 2,3,4-Trihydroxybenzophenone tris(1,2-naphthoquinonediazide-5-sulfonate) [5610–94–6] 2,3,4-Trihydroxybenzophenone 1,2-naphthoquinonediazide-5-sulfonate [68510–93–0].	NIEHS	Moderate production volume; potential worker exposures from production and use of photoresists; lack of adequate toxicological data.	—In vitro toxicity studies evaluating genotoxicity, immunotoxicity and phototoxicity. —Dermal penetration studies.
3-Dimethylaminopropyl methacrylamide [5205–93–6].	NCI	High production volume (HPV); potential worker and consumer exposures; lack of adequate toxicological data; demonstrated toxicity in short-term studies.	—Metabolism and disposition studies. —Genotoxicity studies. —Subchronic toxicity studies. —Coordinate studies with voluntary data development activities of the Extended HPV (EHPV) Program.
Flame retardants Antimony trioxide [1309–64–4] Decabromodiphenyl oxide [1163–19–5].	Consumer Product Safety Commission Staff.	Anticipated increased use in upholstered furniture and bedding and potential consumer exposures from these uses; insufficient toxicity data to assess potential health risks.	See specific chemicals below: —Chronic toxicity studies (oral route). —Consider studies of nanoscale form if used in or released during flame retardant applications. —Developmental neurotoxicity studies. —Studies only to be performed if adequate private sector study not identified or planned.
Tris (chloropropyl) phosphate, mixture of four isomers [13674–84–5; 76025–08–6; 76649–15–5; 6145–73–9].			—Subchronic and chronic toxicity studies (oral route). —Studies to focus on commercial mixture or major isomers present in commercially used mixtures.
Phosphonic acid, (3-((hydroxymethyl) amino)-3-oxopropyl)-, dimethyl ester [20120–33–6].			—Subchronic and chronic toxicity studies (oral route). —Dermal absorption studies.

TABLE 1.—STUDY RECOMMENDATIONS FOR SUBSTANCES NOMINATED TO THE NTP FOR TOXICOLOGICAL STUDIES—Continued

Substance [CAS No.]	Nominated by [1]	Nomination Rationale	Study Recommendations [2]
Tris (hydroxymethyl) phosphine oxide [1067–12–5].	.....	.....	—Subchronic and chronic toxicity studies (oral route). —Dermal absorption studies.
Aromatic phosphates tert-Butylphenyl diphenyl phosphate [56803–37–3] 2-Ethylhexyl diphenyl phosphate [1241–94–7] Isodecyl diphenyl phosphate [29761–21–5] Phenol, isopropylated, phosphate (3:1) [68937–41–7] Tricresyl phosphate [1330–78–5] Triphenyl phosphate [115–86–6].	.....	.....	For one or more representative aromatic phosphates: —Subchronic and chronic toxicity studies (oral route). —Neurotoxicity and/or developmental neurotoxicity studies. —Coordinate with the U.S. Environmental Protection Agency to pursue additional testing by manufacturers.
Gypsum, natural and synthetic forms [13397–24–5].	Mount Sinai-Irving J. Selikoff Center for Occupational and Environmental Medicine Operative Plasterers' and Cement Masons' International Association of the United States and Canada.	Widespread worker exposures in numerous occupations and to the general population after destruction of the World Trade Centers in 2001; limited toxicity data to assess potential health risks.	—Short-term pulmonary toxicity studies. —Comparative studies of intratracheal versus inhalation routes of administration. —Studies are of relatively low priority given low suspicion of toxicity.
N-methyl-3-oxobutanamide [20306–75–6].	NCI	High production volume; potential worker and environmental exposures; lack of adequate toxicological data.	—In vitro and in vivo genotoxicity studies. —Include structurally-related diketene compounds and N-phenyl derivatives.
Phenoxyethyl acrylate [48145–04–6].	NCI	High production volume; potential worker and consumer exposures; lack of adequate toxicological data.	—Defer pending review of voluntary data submission through the Extended HPV (EHPV) Program.
Trifluoromethylbenzene [98–08–8]	NCI	High production volume and potential for increased use; potential worker exposures; lack of adequate toxicological data; demonstrated toxicity in short-term studies.	Defer pending review of 1) production data through the 2006 Toxic Substances Control Act (TSCA) Inventory Update Rule, and 2) Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) program output.

[1] National Institute of Environmental Health Sciences (NIEHS); National Cancer Institute (NCI)

[2] The term ''toxicological characterization'' in this table includes studies for genotoxicity, subchronic toxicity, and chronic toxicity/carcinogenicity as determined to be appropriate during the conceptualization and design of a research program to address toxicological data needs. Other types of studies (*e.g.*, metabolism and disposition, immunotoxicity, and reproductive and developmental toxicity) may be conducted as part of a complete toxicological characterization; however, these types of studies are not listed unless they are specifically recommended.

[FR Doc. E6–5217 Filed 4–10–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4889–N–07]

Change of Effective Date of 2004 Amendatory Notice for Designation of Difficult Development Areas Under Section 42 of the Internal Revenue Code of 1986

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: This notice changes the extended effective date language applicable to 2003 Difficult Development Areas that were not so designated in 2004 in HUD's November 2, 2004, notice to include the date of December 17, 2004, to allow its applicability to projects affected by a misinterpretation of the November 2, 2004, notice on the part of a Low-Income Housing Tax Credit-allocating agency.

FOR FURTHER INFORMATION CONTACT: With questions related narrowly to the issue of the effective dates in this notice, Kurt G. Usowski, Associate Deputy Assistant Secretary for Economic Affairs, Office of Policy Development and Research, 451 Seventh Street, SW., Washington, DC 20410–6000, telephone (202) 708–2770, or e-mail *Kurt_G._Usowski@hud.gov.* A text telephone is available for persons with hearing or speech impairments at (202) 708–9300. (These are not toll-free telephone numbers.)

Copies Available Electronically: This notice is available electronically on the Internet (World Wide Web) at *http://www.huduser.org/datasets/qct.html.*

SUPPLEMENTARY INFORMATION: On December 19, 2003 (68 FR 7092), HUD published in the **Federal Register** the notice designating Difficult Development Areas (DDAs) and Qualified Census Tracts (QCTs) for calendar year 2004 (the 2004 notice). The 2004 notice provided that the lists of Difficult Development Areas are effective if the credits are allocated after December 31, 2003; and, in the case of a building described in section