

institutions to report known or suspected violations of law and suspicious transactions. To fulfill these requirements, supervised banking organizations file SARs. Law enforcement agencies use the information submitted on the reporting form to initiate investigations and the Federal Reserve uses the information in the examination and oversight of supervised institutions.

Current actions: On April 23, 2012, the Federal Reserve published a notice in the **Federal Register** (77 FR 24205) requesting public comment for 60 days on the extension, without revision, of the interagency Suspicious Activities Report by Depository Institutions. The comment period for this notice expired on June 22, 2012. The Federal Reserve did not receive any comments.

Board of Governors of the Federal Reserve System, July 10, 2012.

Jennifer J. Johnson,
Secretary of the Board.

[FR Doc. 2012-17183 Filed 7-12-12; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Public Comment on a Nomination to the Office of Health Assessment and Translation

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for public comment.

SUMMARY: The NTP requests comments on Air Pollution and Children's Health, which was nominated for a possible evaluation by the Office of Health Assessment and Translation (OHAT). This nomination focuses on substances, mixtures, and exposure circumstances (collectively referred to as "substances") related to traffic/near road air pollution and their association with emerging children's health outcomes.

DATES: The deadline for submission of public comments on the nominated substances is August 24, 2012; comments submitted after this date will be considered as time permits.

ADDRESSES: Comments should be sent to Dr. Kembra Howdeshell, Office of Health Assessment and Translation, DNTP, NIEHS, P.O. Box 12233, MD K2-04, Research Triangle Park, NC 27709; telephone (919) 316-4708; FAX: (919) 316-4511; howdeshellkl@niehs.nih.gov. Courier address: NIEHS, Room 2161, 530 Davis Drive, Morrisville, NC 27560.

Comments can also be submitted online at the OHAT Web site (<http://ntp.niehs.nih.gov/go/evals>).

FOR FURTHER INFORMATION CONTACT: Dr. Kembra Howdeshell (telephone: (919) 316-4708 or email howdeshellkl@niehs.nih.gov).

SUPPLEMENTARY INFORMATION:

Request for Public Comment on Nomination to OHAT

The NTP requests public comment on the nomination of Air Pollution and Children's Health for possible evaluation by OHAT. Specifically, the NTP requests information on the following topics: (1) Current exposures and health outcomes considered in this nomination (see list below and the draft literature search strategy provided on the OHAT Web site (<http://ntp.niehs.nih.gov/go/evals>)), (2) published, ongoing, or planned studies related to traffic/near road air pollution and children's health, (3) scientific issues important for assessing emerging health outcomes in children associated with traffic/near road air pollution, and (4) names of scientists with expertise or knowledge about traffic/near road air pollution and children's health. Please include any available bibliographic citations for the information. The NTP will use this information for refining the draft literature search strategy for the nomination prior to a potential formal evaluation by OHAT.

The exposures associated with the nomination include air pollution and the following components: benzene, carbon monoxide, diesel, nitrogen oxides, ozone, particulate matter (PM₁₀, PM_{2.5}, coarse PM, and ultrafine PM), polyaromatic hydrocarbons, and sulfur oxides. The emerging children's health outcomes associated with the nomination include: Incidence and exacerbation of asthma, incidence of allergic disease, adverse birth outcomes (i.e., premature birth, small for gestational age birth weight, and congenital anomalies), respiratory infections in early life, pediatric cancer, development of the nervous system, modifying risk of adult onset diseases (i.e., fetal basis of adult cardiovascular, metabolic or chronic obstructive pulmonary disease), and compromised lung function, development, and growth. Several important air contaminants, including tobacco smoke, mercury, lead, arsenic, indoor aeroallergens, and indoor volatile organic compounds, are not included because they have been addressed in other comprehensive reviews.

Persons submitting public comments are asked to include their name, contact

information, affiliation, and sponsoring organization (if any) and to send them to Dr. Howdeshell (see **ADDRESSES** above). All information received will be posted on the OHAT Web site and the submitter identified by name, affiliation, and sponsoring organization, if applicable. The deadline for submission of public comment is August 24, 2012. Comments and information received after that date will be added to the public record and used by the NTP, as time permits, in refining the literature search strategy and scope of this nomination for potential evaluation by OHAT.

Background Information on OHAT

The NTP and the National Institute of Environmental Health Sciences established the Office of Health Assessment and Translation (OHAT) to serve as an environmental health resource to the public and to regulatory and health agencies. This office conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. OHAT evaluations are published as NTP Monographs. OHAT also organizes state-of-the-science workshops to address issues of importance in environmental health sciences. Information about the OHAT is available on the OHAT Web site (<http://ntp.niehs.nih.gov/go/ohat>) or by contacting Dr. Howdeshell (see **ADDRESSES**).

Dated: July 5, 2012.

John R. Bucher,
Associate Director, National Toxicology Program.

[FR Doc. 2012-17114 Filed 7-12-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Evaluation of In Vitro Tests for Identifying Eye Injury Hazard Potential of Chemicals and Products: Request for Nominations for an Independent Expert Panel and Submission of Relevant Data

AGENCY: Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for Data; Request for Nomination of Scientific Experts.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), is planning to convene an independent scientific peer review panel (Panel) to assess the validation status of *in vitro* tests and integrated non-animal testing strategies proposed for identifying eye injury hazard potential of chemicals and products. On behalf of ICCVAM, NICEATM requests nominations of scientific experts who can be considered for the Panel and submission of data from substances tested in *in vitro* tests for identifying eye injury hazard potential. Of particular interest are data generated in the short-time exposure (STE) (Takahashi *et al.*, 2008) and isolated rabbit eye (IRE) (ICCVAM, 2006, 2010a) tests and data from approaches using two or more *in vitro* tests. However, NICEATM requests data from other tests including, but not limited to, the bovine corneal opacity and permeability (BCOP), isolated chicken eye (ICE), hen's egg test—chorioallantoic membrane (HET-CAM), Cytosensor microphysiometer (CM), fluorescein leakage (FL), SkinEthic™ human corneal epithelium, and EpiOcular™ tests. If available, corresponding *in vivo* data for these substances are also requested, including data from any ethical human or animal studies or accidental human exposures.

DATES: Nominations and test method data for the STE and IRE tests should be submitted by August 27, 2012. Data submitted after this date will be considered in the evaluation where feasible.

FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709, (telephone) 919-541-2384, (fax) 919-541-0947, (email) niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The development of *in vitro* alternatives to animals for eye safety assessments is an ICCVAM priority (ICCVAM, 2008). See <http://iccvam.niehs.nih.gov/methods/ocutox/ocutox.htm> for more information on ICCVAM evaluations of ocular toxicity test methods. An efficient non-animal evaluation of substances for their eye hazard potential is expected to require a number of adequately validated *in vitro* tests that can be considered for use

in integrated testing and decision strategies. *In vivo* reference data and *in vitro* test data for available methods is sought to support the validity of individual methods and to construct integrated testing and decision strategies using multiple methods.

In 2006, ICCVAM evaluated the validation status of the *in vitro* tests BCOP, ICE, HET-CAM, and IRE for their usefulness and limitation for identifying ocular corrosives and severe irritants (ICCVAM, 2006). ICCVAM concluded that BCOP and ICE had sufficient relevance and reliability to support their use for identifying certain types of substances as ocular corrosives and severe irritants for regulatory hazard classification. Subsequently, BCOP and ICE were adopted as Organisation for Economic Co-operation and Development (OECD) Test Guidelines 437 and 438, respectively (OECD, 2009a, 2009b). The IRE and HET-CAM tests lacked sufficient data and/or had insufficient relevance and reliability to support their use for regulatory hazard classification.

In 2009, ICCVAM evaluated the validation status of these four *in vitro* tests for identifying eye injury hazard potential, along with the CM test, to assess their usefulness for identifying nonsevere eye irritants and substances not classified as irritants (ICCVAM, 2010a). ICCVAM concluded that the CM test could be used as a screening test to identify some types of substances that may cause permanent or severe eye injuries. ICCVAM also recommended that the CM test could be used to determine if some types of substances will not cause sufficient injury to require hazard classification for eye irritation. The predictivity of the remaining four *in vitro* tests was considered insufficient to support their use for identifying substances that may cause reversible and nonsevere eye injuries.

ICCVAM also evaluated the validation status of the antimicrobial cleaning products (AMCP) testing strategy, which included the BCOP, CM, and EpiOcular™ tests. ICCVAM concluded that the data were insufficient to adequately demonstrate that the AMCP testing strategy can identify all four U.S. Environmental Protection Agency (EPA) eye hazard categories (ICCVAM, 2010b). An EPA-implemented voluntary pilot program is ongoing to evaluate the use of the AMCP testing strategy for eye irritation labeling for certain antimicrobial products (<http://www.epa.gov/oppad001/eye-irritation.pdf>).

The IRE test is an organotypic test method that evaluates the eye injury

potential of a test substance by measuring corneal opacity, corneal swelling, epithelial integrity, and fluorescein staining. During the previous evaluations of the IRE test, ICCVAM recommended further standardization of the test protocol and additional studies using all four endpoints to expand the IRE test validation database (ICCVAM, 2006, 2010a).

The STE test measures the viability of rabbit corneal epithelial cells following test substance exposure (Takahashi *et al.*, 2008). NICEATM is requesting additional data that can be considered in assessing the validity of the STE and the IRE. Other test methods and integrated testing and decision strategies will also be considered for review if there are sufficient new data available.

For test methods and strategies for which there are sufficient data, ICCVAM will develop draft recommendations on test method usefulness and limitations, standardized test method protocols, future studies that may expand the usefulness of the test method, and test method performance standards. These draft recommendations and supporting data will be provided to the Panel and made available to the public. The Panel will meet in public session to review the validation status of the proposed methods and comment on the extent to which the data support the draft ICCVAM test method recommendations. Meeting information, including dates, locations, and public availability of the meeting documents will be announced in a future **Federal Register** notice and will also be posted on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

Request for Nominations of Scientific Experts

NICEATM requests nominations of scientists with relevant knowledge and expertise to serve on the Panel. Areas of relevant expertise include, but are not limited to biostatistics; human and veterinary ophthalmology, with an emphasis on evaluation and treatment of chemical injuries; *in vivo* eye safety testing; *in vitro* eye safety testing; and test method validation. Each nomination should include the nominee's name, affiliation, contact information (*i.e.*, mailing address, email address, telephone and fax numbers), curriculum vitae, and a brief summary of relevant experience and qualifications.

Request for Data

NICEATM invites the submission of data from substances tested in any *in vitro* test and integrated non-animal

testing strategies proposed for identifying eye injury hazard potential of chemicals and products. If available, *in vivo* reference data for substances tested in these data sets are also requested. Although data can be accepted at any time, please submit data by August 27, 2012 to ensure consideration during the ICCVAM evaluation process. Relevant data received after this date will be considered where feasible. All information submitted in response to this notice will be made publicly available and may be incorporated into future NICEATM and ICCVAM reports and publications, as appropriate.

When submitting data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, email, and sponsoring organization, as applicable). NICEATM prefers that data be submitted as copies of pages from study notebooks and/or study reports, if available. Laboratory data and analyses available in electronic format may also be submitted. Each submission for a substance should preferably include the following information, as appropriate: common and trade name, Chemical Abstracts Service Registry Number (CASRN), commercial source, *in vitro* test protocol used, rabbit eye test protocol used, individual animal or *in vitro* responses at each observation time (*i.e.*, raw data), extent to which the data were collected in accordance with national or international Good Laboratory Practice guidelines, date and testing organization, and physical and chemical properties (e.g., molecular weight, pH, water solubility, etc.)

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, use, generate, or disseminate toxicological and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of testing methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM, provides

scientific and operational support for ICCVAM-related activities, and conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies for validation studies and technical evaluations. Additional information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM Web site (<http://iccvam.niehs.nih.gov>).

References

ICCVAM. 2006. ICCVAM Test Method Evaluation Report: *In Vitro* Ocular Toxicity Test Methods for Identifying Severe Irritants and Corrosives. NIH Publication No. 07-4517. Research Triangle Park, NC: NIEHS. Available: http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_tmer.htm.

ICCVAM. 2008. The NICEATM-ICCVAM Five-Year Plan (2008-2012): A Plan to Advance Alternative Test Methods of High Scientific Quality to Protect and Advance the Health of People, Animals, and the Environment. NIH Publication No. 08-6410. Research Triangle Park, NC: NIEHS. Available: <http://iccvam.niehs.nih.gov/docs/5yearplan.htm>.

ICCVAM. 2010a. ICCVAM Test Method Evaluation Report: Current Validation Status of *In Vitro* Test Methods Proposed for Identifying Eye Injury Hazard Potential of Chemicals and Products. NIH Publication No. 10-7553. Research Triangle Park, NC: NIEHS. Available: <http://iccvam.niehs.nih.gov/methods/ocutox/MildMod-TMER.htm>.

ICCVAM. 2010b. ICCVAM Test Method Evaluation Report: Current Validation Status of a Proposed *In Vitro* Testing Strategy for U.S. Environmental Protection Agency Ocular Hazard Classification and Labeling of Antimicrobial Cleaning Products. NIH Publication No. 10-7513. Research Triangle Park, NC: NIEHS. Available: <http://iccvam.niehs.nih.gov/methods/ocutox/antimicro/TMER.htm>.

OECD. 2009a. Test Guideline 437. Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants [adopted 7 September 2009]. In: OECD Guidelines for the Testing of Chemicals, Section 4: Health Effects. Paris:OECD Publishing. Available: http://www.oecd-ilibrary.org/environment/test-no-437-bovine-corneal-opacity-and-permeability-test-method-for-identifying-ocular-corrosives-and-severe-irritants_9789264076303-en.

OECD. 2009b. Test No. 438. Isolated Chicken Eye Test Method for Identifying Ocular Corrosives and Severe Irritants [adopted 7 September 2009]. In: OECD Guidelines for Testing of Chemicals. Paris:OECD Publishing. Available: http://www.oecd-ilibrary.org/environment/test-no-438-isolated-chicken-eye-test-method-for-identifying-ocular-corrosives-and-severe-irritants_9789264076310-en.

Takahashi Y, Koike M, Honda H, Ito Y, Sakaguchi H, Suzuki H, Nishiyama N. 2008. Development of the short time exposure (STE) test: an *in vitro* eye irritation test using SIRC cells. *Toxicol In Vitro* 22:760-770.

Dated: July 5, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012-17118 Filed 7-12-12; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0114]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 13, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0206. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Food and Drug Administration, 1350 Piccard Dr., PI50-