

**DATES:** April 20, 2007, from 10 a.m. to 3:30 p.m. Eastern Daylight Time.

**ADDRESSES:** Hubert H. Humphrey Building (200 Independence Avenue, SW., Washington, DC 20201), Room 505A (please bring photo ID for entry to a Federal building).

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit/ahic/population/>.

**SUPPLEMENTARY INFORMATION:** The Workgroup will continue deliberation on response management. The meeting will include testimony on Communications, and Countermeasure Allocation, Distribution and Administration tracking during a public health response.

The meeting will be available via Web cast. For additional information, go to: [http://www.hhs.gov/healthit/ahic/population/pop\\_instruct.html](http://www.hhs.gov/healthit/ahic/population/pop_instruct.html).

Dated: March 22, 2007.

**Judith Sparrow,**

*Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 07-1540 Filed 3-28-07; 8:45 am]

**BILLING CODE 4150-24-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the National Coordinator for Health Information Technology; American Health Information Community Electronic Health Records Workgroup Meeting

**ACTION:** Announcement of meeting.

**SUMMARY:** This notice announces the 15th meeting of the American Health Information Community Electronic Health Records Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.).

**DATES:** April 18, 2007, from 9:30 a.m. to 1:30 p.m. (Eastern Daylight Time).

**ADDRESSES:** Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090. Please bring photo ID for entry to a Federal building.

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit/ahic/healthrecords/>.

**SUPPLEMENTARY INFORMATION:** The Workgroup will continue its discussion on ways to achieve widespread adoption of certified EHRs, minimizing gaps in adoption among providers.

The meeting will be available via Web cast. For additional information, go to:

[http://www.hhs.gov/healthit/ahic/healthrecords/ehr\\_instruct.html](http://www.hhs.gov/healthit/ahic/healthrecords/ehr_instruct.html).

Dated: March 22, 2007.

**Judith Sparrow,**

*Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 07-1541 Filed 3-28-07; 8:45 am]

**BILLING CODE 4150-24-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the National Coordinator for Health Information Technology; American Health Information Community Confidentiality, Privacy, and Security Workgroup Meeting

**ACTION:** Announcement of meeting.

**SUMMARY:** This notice announces the ninth meeting of the American Health Information Community Confidentiality, Privacy, and Security Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.).

**DATES:** April 12, 2007, from 1 p.m. to 5 p.m. Eastern Daylight Time.

**ADDRESSES:** Hubert H. Humphrey Building (200 Independence Avenue, SW., Washington, DC 20201), Conference Room 705A (please bring photo ID for entry to a Federal building).

**FOR FURTHER INFORMATION CONTACT:** <http://www.hhs.gov/healthit/ahic/confidentiality/>.

**SUPPLEMENTARY INFORMATION:** The Workgroup Members will continue discussing its working hypothesis, and its evaluation of the privacy and security protections for participants in an electronic health information exchange network at a local, state, regional, or nationwide level.

The meeting will be available via Web cast at [http://www.hhs.gov/healthit/ahic/cps\\_instruct.html](http://www.hhs.gov/healthit/ahic/cps_instruct.html).

Dated: March 22, 2007.

**Judith Sparrow,**

*Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.*

[FR Doc. 07-1542 Filed 3-28-07; 8:45 am]

**BILLING CODE 4150-24-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 preliminary study recommendations regarding nine 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, 2007.

**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](mailto: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 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 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 and may be further refined as the formal review process continues. The NTP 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 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 high-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. Comments should be submitted by May 10, 2007; however, the NTP welcomes comments or additional information on these study nominations at any time. The NTP will not respond to submitted comments; however, all information received will 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 Web site 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 21, 2007.

**David A. Schwartz,**

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

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

Substance [CAS No.]	Nominated by <sup>1</sup>	Nomination rationale	Preliminary study recommendations <sup>2</sup>
Aminopyridines: 2-Aminopyridine [504–29–0], 3-Aminopyridine [462–08–8], 4-Aminopyridine [504–24–5].	NCI .....	Moderate production and use; acutely toxic; lack of adequate toxicological data; suspicion of toxicity and carcinogenicity based on structure.	—Toxicological characterization including chronic toxicity and carcinogenicity studies for 2-aminopyridine. —Short-term mechanistic studies for 3- and 4-aminopyridine. —Comparative neurotoxicity studies for 2-, 3-, and 4-aminopyridine.

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

Substance [CAS No.]	Nominated by <sup>1</sup>	Nomination rationale	Preliminary study recommendations <sup>2</sup>
Artificial butter flavoring mixture and certain components: Acetoin [513–86–0], Diacetyl [431–03–8].	United Food and Commercial Workers International Union.	Evidence of lung disease in exposed workers and respiratory toxicity in short-term animal toxicity studies.	—Chronic toxicity and carcinogenicity studies via inhalation in rats. —Mechanistic studies.
Asbestos, naturally occurring and atypical forms [1332–21–4].	National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, U.S. Environmental Protection Agency.	Widespread community exposure in certain geographic locales; insufficient dose-response data to characterize risk from exposure to “unregulated” asbestiform mineral fibers and naturally occurring fibrous mineral “mixtures”.	—Mineral characterization. — <i>In vitro</i> durability and toxicity studies. —Subchronic and chronic toxicity/carcinogenicity studies via inhalation. —Studies should utilize test materials representative of minerals identified in Libby, MT and at other Naturally Occurring Asbestos (NOA) sites.
Diethyl phthalate [84–66–2] .....	National Institute of Environmental Health Sciences.	Widespread consumer exposure through use in cosmetics and personal care products; insufficient toxicity data to assess potential reproductive hazard.	—Multigeneration oral reproductive and developmental toxicity studies —Toxicokinetic studies (oral and dermal routes).
2',2''-Dithiobisbenzanilide [135–57–9] ....	NCI .....	High production volume; potential worker and consumer exposures; lack of adequate toxicological data; suspicion of toxicity based on structure.	—Genotoxicity studies. —Metabolism studies.
2-Methoxy-4-nitroaniline [97–52–9] .....	NCI .....	High production volume; potential worker exposures; lack of adequate toxicological data; positive mutagenicity data; strong suspicion of toxicity and carcinogenicity based on structure.	—Toxicological characterization. —Short-term mechanistic studies to predict carcinogenic potential.
Nanoscale materials Nanoscale gold [7440–57–5] Nanoscale silver [7440–22–4].	U.S. Food and Drug Administration.	Widespread and increasing use in drug, food and cosmetic products; lack of adequate toxicological and pharmacokinetic data; need to evaluate whether the current required tests are adequate to detect adverse biological and toxicological events.	—Nanoscale materials characterization. —Metabolism and pharmacokinetic studies. —Acute, subacute and subchronic toxicity studies. —Mechanistic studies to assess the role of size and surface coating on biological disposition and toxicity.
Pentaethylenehexamine [4067–16–7] ....	NCI .....	High production volume; potential worker exposures; lack of adequate toxicological data; positive mutagenicity data.	No studies at this time due to the irritant and corrosive nature of this compound.
o-Phthalaldehyde [643–79–8] .....	National Institute for Occupational Safety and Health.	Widespread and increasing use as a disinfectant in health care settings; lack of adequate and publicly available toxicological data; potential skin and respiratory sensitizer.	—Toxicological characterization including studies to assess dermal irritation, dermal toxicity, and sensitization and asthmagenic potential.

<sup>1</sup> National Cancer Institute (NCI).

<sup>2</sup> 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.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 1997E–0013]

**Determination of Regulatory Review Period for Purposes of Patent Extension; RETEVASE**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for RETEVASE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human biological product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets