DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine, Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the fourth meeting of the Commission on Systemic Interoperability. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The mission of the Commission on Systemic Interoperability is to submit a report to the Secretary of Health and Human Services and to Congress on a comprehensive strategy for the adoption and implementation of health care information technology standards that includes a timeline and prioritization for such adoption and implementation. In developing that strategy, the Commission will consider: (1) The costs and benefits of the standards, both financial impact and quality improvement; (2) the current demand on industry resources to implement the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and other electronic standards, including HIPAA standards; and (3) the most cost-effective and efficient means for industry to implement the Standards.

Name of Committee: Commission on Systemic Interoperability.

Date: April 22, 2005.

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

Agenda: Healthcare Information Technology Standards.

Place: Hubert H. Humphrey Building, Room 800, 200 Independence Avenue, Washington, DC 20250.

Contact Person: Ms. Dana Haza, Director, Commission on Systemic Interoperability, National Library of Medicine, National Institutes of Health, Building 38, Room 2N21, Bethesda, MD 20894, 301-594-7520.

dated: March 24, 2005.

LaVerne Y. Stringfield,
Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP); Liaison and Scientific Review Office (LSRO); Announcement of National Toxicology Program (NTP) Workshop on “Animal Models for the NTP Rodent Cancer Bioassay: Strains & Stocks—Should We Switch?”

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

ACTION: Meeting Announcement.

SUMMARY: Over the past year, the National Toxicology Program (NTP) has developed and refined a vision for toxicology in the 21st century (“NTP Vision”) and a roadmap for implementing this vision (“NTP Roadmap”) that will strategically position the program at the forefront for providing scientific data and the interpretation of those data for public health decision-making (see additional detail). As part of the NTP Roadmap, the program will convene a series of public workshops to review aspects of the existing testing program. The first workshop is scheduled for June 16–17, 2005, at the NIEHS in Research Triangle Park, NC and will focus on evaluating stocks and strains currently used in the NTP rodent cancer bioassay in order to improve the ability of the bioassay to identify substances that may pose a carcinogenic hazard for humans. In particular, the goal of this workshop is to seek scientific input as to whether the NTP should continue to use both the F344 rat and B6C3F1 mouse models, use other strains, and/or use multiple strains as previously suggested (Festing, 1995). Future workshops will address other study design issues such as diet, length of study, and age at exposure. The NTP invites public comments on the appropriateness of the F344N and B6C3F1 models currently used and the submission of historical control data for rodent models that the NTP might consider at the workshop. The program will include plenary sessions as well as three breakout group meetings for in-depth discussions of rat models, mouse models, and the multiple strain approach. Following the meeting, the NTP will prepare a workshop report and present its proposed testing strategy to the NTP Board of Scientific Counselors for their consideration and input.

Attendance at the meeting is limited only by the space available. Members of the public may register to attend the workshop on a first-come, first-served basis per the procedures outlined below. A copy of the agenda and any additional information on the workshop, including participants and background materials, will be posted on the NTP Web site when available (http://ntp.niehs.nih.gov select “Meetings and Workshops”).

DATES: The workshop will be held June 16–17, 2005. The meeting will begin at 8:30 a.m. each day and end at 5 p.m. on June 16 and approximately 12 p.m. on June 17.

Comments: Written comments and historical control data should be received by May 19, 2005, to enable review by NIEHS/NTP staff and workshop panelists prior to the meeting (see FOR FURTHER INFORMATION CONTACT below). The deadline for registration to present oral comments at the meeting is June 9, 2005.

Registration: Individuals who plan to attend are strongly encouraged to register by June 9, 2005, in order to ensure access to the NIEHS campus (see FOR FURTHER INFORMATION CONTACT below). Persons needing special assistance, such as sign language
interpretation or other reasonable accommodation, in order to attend are asked to notify the NTP at least 7 business days in advance of the meeting.

**ADDRESSES:** The meeting will be held in the Rodbell Auditorium, Rall Building at the National Institute of Environmental Health Sciences, 11 T.W. Alexander Drive, Research Triangle Park, NC 27709.

**FOR FURTHER INFORMATION CONTACT:** Public comments, data submission and any other correspondence should be submitted to Dr. Angela King-Herbert (NIEHS, P.O. Box 12233, MD B3–06, Research Triangle Park, NC 27709; telephone: 919–541–3464, fax 919–541–7666; or e-mail: kingher1@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Background on the NTP Vision and Roadmap to Achieve the Vision**

The NTP was established in 1978 to coordinate toxicological testing programs within the Department of Health and Human Services, develop and validate improved testing methods, develop approaches and generate data to strengthen scientific knowledge about potentially hazardous substances and communicate with stakeholders. In its more than 25 years of existence, NTP has become a world leader in providing scientific information that improves our nation’s ability to evaluate potential human health effects from chemical and physical exposures. The NTP maintains a number of complex, interrelated research and testing programs that provide unique and critical information needed by health regulatory and research agencies to protect public health.

The last decade of the 20th century and the turn of the 21st century have produced dramatic technological advances in molecular biology and computer science. The NTP is ready to evaluate its key activities and, in a focused and concerted effort, determine how best to incorporate these new scientific technologies into its research and testing strategies and broaden scientific knowledge on the linkage between mechanism and disease. In August 2003, the NTP defined its vision for the 21st century and undertook a yearlong process to refine that vision and develop a roadmap for its implementation. The NTP Vision is to support the evolution of toxicology from a predominately observational science at the level of disease-specific models to a predominately predictive science focused upon a broad inclusion of target-specific, mechanism-based, biological observations. The NTP roadmap for implementation of the vision will strategically position the program at the forefront for providing scientific data and the interpretation of those data for public health decision-making. The NTP Roadmap was developed with input from numerous groups including its federal partners, its advisory committees, and the public. In carrying out the NTP Roadmap, the program plans to formally review the designs of NTP assays to determine whether protocol changes are needed. Additional information about the NTP Vision and Roadmap is available on its Web site (http://ntp.niehs.nih.gov/ntp select “NTP Vision and Roadmap”).

The NTP periodically conducts reviews of animal models used in the NTP cancer bioassay including recent evaluations on the use of fish and transgenic mouse models as alternative approaches (Board of Scientific Counselors, 2004; NTP Board of Scientific Counselors Technical Reports Review Subcommittee, 2003; Scientific Advisory Committee on Alternative Toxicological Methods, 2004). However, the last formal review of the NTP rodent bioassay occurred in August 1984 (Report of the Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation of the NTP Board of Scientific Counselors, August 17, 1984). Although the NTP has expanded the breadth of its evaluation of individual agents and the number of endpoints critically assessed in the bioassay, the rodent cancer bioassay study design has been minimally modified over the past 30 years. For this reason, the program intends to convene a series of workshops to evaluate the rodent cancer bioassay, beginning with choice of species and strain. Future workshops will address other study design issues, such as diet, study length, and age at exposure. The ultimate goal of any change to the NTP cancer bioassay is to improve the identification of carcinogenic potential (i.e., hazard identification) and/or improve our ability to predict cancer in humans.

**Request for Comments**

Public input at this meeting is invited and time is set aside for the presentation of public comments on any agenda topic. Each organization is allowed one time slot per agenda topic. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes. Registration for oral statements can supplement and may expand the oral presentation. If registering on-site and reading from written text, please bring 40 copies of the statement for distribution and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site (http://ntp.niehs.nih.gov select “Meetings and Workshops”). Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document. Individuals wishing to submit historical control data are encouraged to contact Dr. Angela King-Herbert prior to submission (see FOR FURTHER INFORMATION CONTACT above).

**References**


Dated: March 22, 2005.

**Samuel H. Wilson,**

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–6605 Filed 4–1–05; 8:45 am]

**BILLING CODE 4140–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Office of the Director; Office of Dietary Supplements: Notice of Opportunity for Public Comment and Public Meeting**

**Background**

The Office Dietary Supplements (ODS) was established in the Office of