National Toxicology Program
Board of Scientific Counselors

August 18, 2005

NIEHS, Research Triangle Park, NC

Summary Minutes

I. Attendees

NTP Board of Scientific Counselors:

Members:
Diane Birt
Aaron Blair
Gail Charnley
Harvey Checkoway
George Daston
Elizabeth Delzell
Michael Elwell
John Giesy
Maria Morandi
Charlene McQueen
Barbara Pence
James Popp (Chairperson)
Stephen Roberts
Mary Vore
Bruce Weir

Board Members not attending:
Thomas Gasiewicz
Shuk-Mei Ho
Cheryl Walker

***ad hoc* member**
Kim Boekelheide

NIEHS Staff in Attendance:
Jack Bishop
Gary Boorman
Douglas Bristol
Michelle Hooth
John E. French
Paul Foster
William Jameson
Gloria Jahnke
Shawn Johnston
Grace Kissling
David Malarkey
Robert Maronpot
Deborah McCarley
Daniel Morgan
Abraham Nyska
Denise Orzeck
John Pritchard
Cynthia Smith
Stanley Stasiewicz
Fernando Suarez
Julius Thigpen
Molly Valant
Nigel Walker
Kristine Witt
Mary Wolfe

Other Federal Agency Staff:
William Allaben, FDA
Mark Toraason, NIOSH

Public:

Stan Atwood, Constella Group
Andrew Ballard, BNA
Brad Blackard, ILS/NICEATM
Beth Carroll, Syngenta Corporation
Greg Carter, Constella Group
Jeff Charles, ILS/NICEATM
Sanford Garner, Constella Group
Dana Greenwood, Constella Group
Reshan Fernando, RTI International
Robert Kavlock, EPA
William G. Kelly, Jr., Center for Regulatory Effectiveness (CRE)
Susan Kinney, ILS
George Krautter, RJR
Alan Levesgne, ILS
Dawn McIntyre ILS/NICEATM
E. Pellizzari, RTI International
Catherine Price, RTI International
James Raymer, RTI International
Ken Rehder, RTI International
Scott Slaughter, CRE
C. Sparacerni, RTI International
William Studabaker, RTI International

II. Introductions and Welcome

The National Toxicology Program (NTP) Board of Scientific Counselors ("the Board") met on August 18, 2005, at the National Institute for Environmental Health Sciences (NIEHS), Research Triangle Park, North Carolina. (*Attachment 1*: *Federal Register* meeting announcement; *Attachments 2* and *3*: Agenda and Roster of Members). Dr. James Popp, Chair, welcomed everyone to the meeting and asked the Board members and attendees to introduce themselves. Dr. Christopher Portier, Associate Director of the NTP, NIEHS, welcomed and thanked the Board members for their attendance and service to the NTP.

Dr. Popp introduced Dr. David Schwartz, who became the new director of the NIEHS and the NTP in June. Dr. Schwartz thanked the Board for its guidance in making the NTP a stronger program. He talked briefly about the future of the NIEHS and the NTP. He said the NTP's strategic plan fits into the strategic plan for the NIEHS. He is interested in the relationship between the pathophysiology of disease and public health and believes that studying susceptible populations - either those who have a genetic predisposition or those exposed to high concentrations of pollutants - will provide insights into disease causation. He also wants the NIEHS to focus on training interdisciplinary scientists and believes this will facilitate and strengthen the research program in environmental health sciences.

Dr. Schwartz said it is important for the NIEHS to emphasize comparative biology and study multiple organisms as models to understand disease. He is excited that the NTP plans to initiate a program in high throughput screening and embrace model systems such as cells, *Caenorhabditis elegans,* and *in vitro* toxicology. He is hopeful that the NIEHS' intramural program can interact more closely with the extramural community. Dr. Schwartz said the NIEHS established a website to solicit ideas from the public on areas they perceive as important for NIEHS to study; he invited the Board members to provide input. He concluded by noting that the NIEHS would hold a strategic planning meeting

with its stakeholders on October 16-17 to identify critical areas for future NIEHS research endeavors.

Board Comments
Dr. Aaron Blair said it is important to determine the concentration of chemicals to which people are exposed and asked whether the NIEHS would focus on ways to improve the characterization of human exposure. Dr. Schwartz responded that there are opportunities to link experimental and observational studies. For example, he said cells from exposed humans could be studied to assess exposure and dose-response relationships. He said there has been more emphasis on genetic studies and less on epidemiology and exposure because scientists have not had suitable instrumentation to measure exposure. He is proposing studies to monitor populations for extended periods of time to obtain information on biomarkers of exposure for correlation with genetic and phenotypic data. There are two initiatives being discussed by funding agencies: one to develop monitoring tools to assess continuous exposure and the second to monitor people for extended periods of time. Dr. George Daston asked whether these initiatives would be integrated with the NIH Children's Health Study. Dr. Schwartz said there are ongoing discussions to link the programs but at present no decision has been made. Dr. Daston said a problem with biomonitoring data is that it is not informative for risk assessment, because the internal dose is not known and such calculations require sophisticated pharmacokinetic models. Dr. Schwartz responded that he is hopeful NIEHS would develop these models. Dr. Mark Toraason, NIOSH, said his agency has developed new methodology to collect data on exposure. Dr. Popp thanked Dr. Schwartz for providing his perspectives.

Dr. Schwartz then presented certificates of appreciation to Drs. Aaron Blair, Gail Charnley, Harvey Checkoway, Barbara Pence, Jim Popp, Steve Roberts, Mary Vore, and Bruce Weir whose terms on the Board would end on December 31. He acknowledged their outstanding service to the NTP.

III. NTP Update

Dr. Portier thanked the Board for its advice and role in developing the NTP Roadmap. He briefly highlighted some recent NTP activities and provided a status update on others.

A. Recent NTP Meetings

- The NTP held a workshop, "Animal Models for the NTP Rodent Cancer Bioassay: Strains and Stocks - Should We Switch?" on June 16-17, 2005 at the NIEHS. Dr. Portier noted that Dr. Angela King- Herbert, NIEHS, would provide a report later in the meeting.

- The NTP Center for Environmental Research into Human Reproduction (CERHR) held an expert panel meeting on styrene in June. The expert panel report is posted on the CERHR website. CERHR will convene an expert panel in October to update the previous review on di-ethylhexylphthalate; the draft report

is available on the CERHR website. The expert panel reports for amphetamine and methylphenidate and the NTP-CERHR monographs for fluoxetine and acrylamide are on the CERHR website. CERHR sponsored a symposium, "Gene Environment Interaction in Rare Diseases that include Common Birth Defects," on Tuesday June 28 at the Annual Teratology Society Meeting.

- The NTP Center for the Evaluation of Alternative Toxicological Methods (NICEATM) sponsored two scientific symposia on acute ocular toxicology on May 11-13, 2005 on the NIH campus in Washington DC: one on mechanisms of chemically induced ocular injury and recovery, and a second on minimizing pain and distress in ocular toxicology testing. The main goals of the symposia were to review the state-of-the science and the pathophysiology and mechanisms of chemically induced ocular injury and recovery (reversibility versus irreversibility) in order to advance the development of test systems to meet regulatory testing requirements. NICEATM is co-sponsoring the 5th World Congress on Alternatives and Animal Use in the Life Sciences in Berlin on August 21-25, 2005. NICEATM, in cooperation with the International Society for Regulatory Toxicology and Pharmacology, the Doris Day League, and the American Chemical Council will co-sponsor a workshop, "Progress and Barriers to Incorporating Alternative Toxicological Methods in the U.S." in Baltimore, MD on November 17-18, 2005.

B. Other Activities:

- Dr. Portier said the 11th Report on Carcinogens was released on January 31, 2005, and the NTP website had over a million hits that day. More than 400 newspapers covered its release.

- The NTP's High Throughput Screening (HTS) Initiative has had a boost due to the NTP's invitation to participate in the NIH Molecular Libraries Initiative (MLI), which is part of the NIH Roadmap. One of the aims of the MLI is to produce chemical probes to deconstruct the complexity of the genome. The MLI has established a network of nine extramural screening centers that plan to test 120,000 chemicals per year using 100 assays with 100 different endpoints. The NTP will provide guidance on toxicological endpoints that would be of interest and suggest suitable HTS assays to measure these endpoints. The NTP has shipped 400 chemicals, for which it has extensive toxicological data, to NIH for testing. Chemicals selected by NTP for the MLI to study must be soluble in DMSO. The MLI uses 1536-well plates and researchers are able to inject 1408 different chemicals of the same concentration with controls on each plate. They plan to run 15 concentrations of every chemical through every assay.

- The NTP has established collaboration with the Computational Toxicology Group at the EPA in Research Triangle Park to develop methods for data collection and

analysis from the HTS initiative. Formal agreements have been developed for this group to undertake toxicokinetics on compounds of interest.

- Dr. Portier noted that the NTP had worked extremely hard over the past two years with the National Institute for Standards and Technology on development of a system to expose animals to electromagnetic radiation from cellular phones and now these studies are getting underway.

- Dr. Portier identified new staff within the NTP. The *C. elegans* program led by Dr. Jonathan Freedman would move from Duke University to NIEHS. This initiative will focus on the feasibility of this model for medium throughput toxicology screening. Drs. Paul Foster and Michael Wyde have joined the Toxicology Operations Branch. Dr. Foster is the lead scientist for reproductive and developmental biology studies and Dr. Wyde is a study scientist in the carcinogen bioassay group

- Dr. Portier recognized staff that had received awards.
    - Ms. Kennita Johnson received a young investigator award at the Annual Meeting of the Society of Toxicology and Pathology for her poster on imaging in cardiotoxicology and teratology.

    - Dr. Julia Gohlke received the James C. Bradford Memorial Award at the Teratology Society meeting for her poster on gene interaction networks that are modulated during development of the cerebral cortex.

    - Dr. Hiroyoshi Toyoshiba and co-workers received an award from the Dose Response Specialty Section at the Society of Toxicology Annual Meeting for their poster entitled, "Gene interaction networks suggests dioxin induces a significant linkage between aryl hydrocarbon receptor and retinoic acid receptor beta."

    - Dr. Paul Foster received an award from the Reproduction Specialty Section at SOT for his talk on "Dose dependant alterations in gene expression and testosterone synthesis in the fetal testis of male rats exposed to di-ethylhexylphthalate."

C. Toxicogenomic Data in Technical Reports

Dr. Portier sought advice from the Board on the inclusion of toxicogenomic data in NTP Technical Reports. Presently, toxicity studies, immunology, and reproductive toxicology data are included in the NTP technical reports and not reported separately. The NTP has published toxicogenomic studies on substances being tested for carcinogenicity in the peer-reviewed literature. The toxicogenomic data are stored in the Chemical Effects in Biological Systems (CEBS) database, which will be linked to the NTP databases.

Board Discussion
The Board agreed that the NTP Technical Report on a specific substance should be comprehensive and include any toxicogenomic data. Dr. Daston said such a comprehensive report would accomplish two goals: (1) it would provide a means for demonstrating the power of genomics and how such data can be linked to the pathological findings of a specific substance and (2) it would provide a means for summarizing extensive toxicogenomic data that cannot be included in journal articles. Dr. Popp said the NTP has an opportunity to develop a paradigm for summarizing toxicogenomic data and such a document and format are desperately needed.

IV. Peer Review Guidelines: Implication for the NTP

Dr. Portier outlined how the Office of Management and Budget's (OMB's) new guidelines for peer review could affect NTP review processes. He said the NTP has reviewed the guidelines and considered their application to NTP products including RoC background documents and substance profiles, NTP-CERHR monographs, NTP Technical Reports, and alternative toxicological test methods recommended by ICCVAM. He said the NTP would like to develop a generic process for peer review of all scientific publications that it disseminates. The OMB guidelines apply to peer review of the scientific content and not to any opinion that the NTP might offer in its documents.

Dr. Portier briefly outlined the current process for preparation and review of draft NTP Technical Reports and said he believes that the peer review process for these documents complies with OMB guidelines.

Dr. Portier continued by discussing in detail the process for preparation of the RoC and some general considerations for peer review. He said background documents and the 1-2 page substance profiles found in the RoC would now undergo peer review. He clarified that if a group helps develop a document then they cannot participate in its peer review. The NTP is considering using special emphasis panels (SEPs) comprised of scientific experts instead of the Board to review background documents. He said the public would have an opportunity to nominate experts to serve on the SEPs. The SEP meetings would be more in-depth than the RoC Subcommittee meetings and only 2-3 chemicals would be reviewed over a period of 2-3 days. Dr. Portier said following completion of the peer review, the SEP would be asked for its recommendation on the listing status for the substance. He said the review by the SEP would precede meetings of the internal government review groups, which under the current RoC review process, met before the RoC Subcommittee. Following these reviews, the NTP would draft the substance profiles and is considering using the NTP Board for their review.

Public Comment
Mr. William Kelly, representing the Center for Regulatory Effectiveness, sent written comments which were distributed to the Board and posted on the NTP website prior to the meeting, and presented oral remarks. He said the OMB guidelines could call for a

separate review of "influential" scientific assessments from "highly influential" scientific assessments. If agencies make this distinction they must give a rational explanation as to why a substance or decision is classified as "influential" or "highly influential." Mr. Kelly believes that the NTP should not differentiate between these two types of assessments. Although some substances recommended for inclusion in the RoC are controversial and others are not, all substances should have the same time allotted for review. He believes the Board has a significant role in suggesting individuals with specific expertise to serve on the panels that review the background documents. He also suggested that societies with specific expertise be consulted to suggest members for the review panels.

Board Discussion
Dr. Barbara Pence responded to Dr. Portier's comment regarding the participation of Board members at different stages of the RoC process and said she served on a NIH subcommittee involved in the initial review of program projects. The subcommittee compiles a report on the review that is brought to the parent committee. At least two members of the subcommittee are members on the parent committee, which makes for continuity in the process of review.

Dr. Maria Morandi said other agencies such as EPA permit a multi-step review of a specific document by the Science Advisory Board (SAB) and questioned why the NTP would not use a similar process.

One member asked how the change in the process for the RoC would affect its cost of preparation and its timeline for completion. Dr. Portier responded that it would likely be more costly and the timeline would be longer. Dr. Blair suggested that if the Board is involved in only one step in the process, then it should have oversight in the other steps.

Dr. Portier then posed two questions to the Board regarding preparation of the RoC:

1. Is it feasible to ask the SEP to make a recommendation regarding listing status based on a draft background document that they have just peer reviewed and any additional relevant information, or must they have the final background document?

The Board offered different opinions on this issue. Dr. Elizabeth Delzell, who served on the RoC Subcommittee, felt that the group should have the final background document to make its recommendation on listing status. Dr. Birt disagreed and said the review panel should have the flexibility of making their recommendation at the meeting. Drs. Stephen Roberts and Blair agreed with Dr. Birt. Dr. Popp, who also served on the RoC Subcommittee, said that based upon his experience, he felt that generally the panel would be able to make a recommendation on a substance's listing status at the same meeting where its background document was reviewed. However, the panel should have flexibility and not be forced to do so. Dr. Portier said that if a recommendation is not made at the SEP meeting on a substance's listing, a second physical meeting would be required.

2. Would the Board prefer to have a role early in the review process or in the later stage? Would the Board be the most appropriate group to review the draft substance profiles?

Dr. Blair thought that the Board should serve as the reviewer of the draft substance profiles. Dr. Daston agreed and said this role fits with its responsibility for oversight of NTP processes and outputs.

Dr. Barbara Pence asked what would happen if the Board disagreed with the decision or information in the profiles. Dr. Portier said the Board would review the scientific information justifying the NTP listing decision, but not the decision. The Board would have the background document, public comments, and the SEP panel's and intra-governmental groups' recommendations as supporting documentation. The Board would not vote on the listing, but could question the NTP's scientific support for the listing.

V. NTP Board of Scientific Counselors Technical Reports Review Subcommittee

Dr. Roberts, representing the Subcommittee, summarized the actions on seven draft NTP Technical Reports reviewed at the meeting on December 9, 2004. The Subcommittee reviewed reports on 3'-azido-3'thymidine, benzophenone, bromodichloromethane, 2,2',4,4',5,5'-hexachloro-biphenyl (PCB 153), a PCB mixture of 3,3',4,4',5 pentachlorobiphenyl (PCB 126) and 2,2',4,4',5,5'-hexachloro-biphenyl (PCB 153), a PCB mixture of 3,3',4,4',5 pentachlorobiphenyl (PCB 126) and 2,3',4,4',5 pentachlorobiphenyl (PCB118), and sodium chlorate. All the studies were performed using the conventional F344 rat and B6C3F$_1$ mouse models. He noted that the Subcommittee addressed the issue of PCB 126 being found as a contaminant in PCB 118 after the study had commenced.

Board Discussion
The Board requested that in future the votes of the Subcommittee be included in the summary statements. The subcommittee unanimously approved the draft NTP conclusions for all the reports except for 3'-azido-3'thymidine where there were 7 yes votes, 0 no votes and two abstentions.

Since the PCB 118 was contaminated with PCB 126 and PCB 126 was shown previously to be a potent carcinogen, Dr. Daston said one could not determine if PCB 118 is a carcinogen or not. Dr. Nigel Walker, NIEHS, said the NTP is now conducting a study of uncontaminated PCB 118.

Dr. Mary Vore proposed and Dr. Diane Birt seconded the motion that the Board vote *en bloc* to accept all the Subcommittee's recommendations on the draft NTP Technical Reports. The motion passed unanimously with 13 yes votes.

One member asked why the NTP is using the p53 and Tg.AC mouse models for carcinogenicity studies. Dr. Bucher responded that the NTP is evaluating whether these models are more sensitive than the conventional mouse models for identification of carcinogenic hazards. He said the NTP is using them in special situations; for example, the testing of drinking water contaminants for the EPA. He noted that the Board discussed the utility of transgenic models at previous meetings.

VI. NTP Study Nominations and ICCEC Recommendations

Dr. Scott Masten, NIEHS, briefly outlined the review and selection process for substances nominated for study by the NTP. He noted that the process includes review by multiple advisory groups and opportunities for public comment. Following review by the Interagency Committee for Chemical Evaluation and Coordination (ICCEC), the NTP announces preliminary study recommendations for each nomination in a Federal Register notice and solicits public comments. Next, the Board reviews the nominations and study recommendations followed by the NTP Executive Committee. Once a nomination is selected, studies are initiated as time and resources permit.

Dr. Masten said 15 new nominations are currently under review; 11 are recommended for study, 3 for deferral, and no studies are recommended at this time for one nomination. He identified the nominations based on their primary use/exposure scenario:

1. Dietary supplements (5): Acetyl-L-carnitine and α-Lipoic acid, *Garcinia cambogia* extract, Gum guggul extract, Usnic acid and Usnea herb, Vincamine
2. Consumer products (4): Butylparaben, 3-Dimethylaminopropylamine, Imidazolidinyl urea, Permanent Makeup Inks
3. Industrial chemicals (6): Antimony trisulfide, Antimony trioxide, 4-Bromofluorobenzene, 2,6-Diaminopyridine, 1,3-Dichloropropanol, 2,5-Dimercapto-1,3,4,-thiadiazole

Board Discussion
Prior to the meeting, the NTP asked individual Board members to serve as lead discussants for specific nominations.

Acetyl-L-carnitine and α-Lipoic acid
The Board agreed with the recommendations to study each compound individually and in combination in subchronic toxicity studies, but questioned whether this nomination should have a high priority for testing. They questioned whether a focus on the effects on the thyroid gland is warranted when there is no direct evidence for thyroid perturbation.

Antimony trioxide and Antimony trisulfide
Antimony trioxide and antimony trisulfide were discussed together. Antimony trioxide is recommended for chronic toxicity, carcinogenicity, and cardiotoxicity studies; for antimony trisulfide no studies are recommended at this time. The Board agreed with the recommendations for antimony trioxide, especially since antimony compounds have been

suggested for use as flame-retardants in home furnishings. The Board agreed with the recommendations not to study antimony trisulfide at this time.

Dr. Torasson asked how the possible cardiotoxic effects of antimony trioxide would be evaluated. Dr. Bucher said the NTP is developing methodology to study the pathological and functional aspects of cardiotoxicity using model compounds including ephedra, caffeine, and bis(2-chloroethoxy)methane. The effects of antimony trioxide might be subtle and might involve changes in the peripheral vasculature; a change that is more difficult to measure than morphological changes of the heart. Dr. Popp questioned whether the study of antimony trioxide is needed since the EPA seems satisfied with the information available for risk assessment. Dr. Masten replied that the EPA considers the database to be inadequate for developing a unit risk for carcinogenicity. He said the Consumer Product Safety Commission supports studies on flame retardant chemicals, and Dr. Torasson concurred that NIOSH would find these studies useful.

4-Bromofluorobenzene
The Board agreed with the recommendation that studies on 4-bromofluorobenzene be deferred until additional information, which is anticipated through the high production volume (HPV) chemical initiative, is available. Dr. Pence said this compound is an orphan chemical for which little information is available except on its acute toxicity in rats and its non-mutagenic response in the Ames assay. Due to its structure, there is concern regarding possible adverse effects from exposure, but she agreed that studies should be deferred until the additional information is available.

Butylparaben
Dr. Kim Boekelheide, an *ad hoc* member of the Board, supported the recommendation that toxicological characterization of butylparaben, including reproductive toxicity studies, be undertaken. He said butylparaben is a member of a group of compounds with ubiquitous exposure. Since metabolism may vary with different routes of exposure, metabolism studies need to be included in any experimental design. Dr. Pence noted that butylparaben is used in many baby products and she suggested that the NTP undertake studies with neonates and immature animals. Dr. Boekelheide suggested that the NTP consider a continuous breeding study. Dr. Cheryl Walker, who did not attend the meeting, submitted written comments. She said butylparaben binds to the estrogen receptor, but since its mode of action is unknown, she did not support studying it. Dr. Masten mentioned unpublished data the NTP received during the public comment period showing that a larger percentage of butylparaben is absorbed through human skin compared to rat skin and that the extent of metabolism is lower in the human than the rat. Dr. Morandi noted the significant potential for dermal exposure to the general population.

2,6-Diaminopyridine
The majority of the Board agreed with the recommendation to defer studies of 2,6-diaminopyridine because of limited data on exposure through its use in hair dyes. Dr. Delzell opined that 2,6-diaminopyridine might not be the most important component of hair dyes to study. She agreed with the proposed deferral because of the lack of data on

exposure. However, Dr. Blair disagreed with the recommendation because over 50% of women use hair dyes, some components of which have been associated with bladder cancer. He said hairdressers also might be exposed. Dr. Popp questioned if deferral is appropriate due to the lack of information on exposure, because other nominations with little information on exposure are proposed for study.

1,3-Dichloropropanol
The Board agreed with the recommendation to study the toxicological effects of 1,3-dichloropropanol. The Board agreed with the proposal to include evaluations of reproductive toxicity, metabolism/disposition, and carcinogenicity because 1,3-dichloropropanol has been reported to cause a significant increase in carcinomas in an unpublished study, little is know about its metabolism or potential reproductive toxicity, and the general population is exposed to this chemical as a food contaminant.

2,5-Dimercapto-1,3,4-thiadiazole
2,5-Dimercapto-1,3,4-thiadiazole is recommended for genotoxicity, metabolism/disposition, and subchronic toxicity studies. The Board did not believe it is a high priority chemical for study although it is a reactive compound, is used as a fire fighting chemical, and has been tested experimentally for use as an antidote to arsenic toxicity. The Board suggested, however, that studies on its mode of action might be useful as well as a study of a cohort of exposed fire fighters. There was disagreement regarding whether occupational or general population exposure is a potential health concern.

3-Dimethylaminopropylamine
The Board agreed with the recommendation to focus studies on dermal absorption, genotoxicity, and its metabolism to a nitrosamine intermediate. The Board was not clear why nitrosation potential is of concern and recommended that the NTP more clearly articulate the rationale for this aspect of the recommended studies.

Garcinia cambogia Extract
The Board agreed with the recommendation to defer study until recent reports of the main active ingredient of the extract, hydroxycitric acid, is carefully reviewed. Hydroxycitric acid is a competitive inhibitor of the Krebs cycle enzyme ATP citrate lyase. The known pharmacology of hydroxycitrate suggests the potential for toxicity and is a reason for concern. The concentration, bioavailability and toxicity of hydroxycitrate in *Garcinia cambogia* extracts appear to differ with the procedure used to prepare the extract and among different commercial products. The Board agreed that it is a high priority for study and should be studied pending a decision on the type of studies to conduct and the source of the extract. They stressed that deferral time should be short because *Garcinia cambogia* extract appears to be replacing ephedra as a popular dietary supplement for weight loss.

Gum Guggul Extract
The Board agreed with the planned toxicological characterization, and suggested that reproductive studies be added because the extract contains steroidal compounds that bind to nuclear hormone receptors that could cause alterations in reproduction and cholesterol biosynthesis.

Imidazolidinyl Urea
The Board agreed that imidazolidinyl urea should be studied for potential mutagenicity, because it may degrade or be metabolized to formaldehyde. The Board agreed that studies to identify its degradation products should be undertaken as well as studies on its dermal absorption since imidazolidinyl urea is used widely in personal care products.

Permanent Makeup Inks
The Board agreed with the recommendation that the NTP study these products for *in vitro*/*in vivo* allergenicity, photoallergenicity, and phototoxicity. Dr. Blair asked whether these permanent inks are the same as those used in tattoos, and Dr. William Allaben, FDA, said in many cases they are. Dr. Blair suggested that perhaps these compounds could be measured directly in people with tattoos since leukocytes are thought to phagocytize them. Dr. Morandi agreed with the recommendations for testing, but thought that a stepwise approach would be best: to first obtain chemistry information on the composition of the inks and then conduct allergenicity studies coupled with pharmacokinetic evaluations.

Usnic acid and Usnea herb
The Board agreed with the recommendations to conduct toxicological characterization studies including genotoxicity, pharmacokinetics, developmental and reproductive toxicity, and *in vitro* mitochondrial toxicity studies. Dr. Birt suggested that testing be undertaken in both sexes of rats and mice and that both pure usnic acid and an *Usnea* herb extract be evaluated. Dr. Charlene McQueen agreed, but said the primary focus should be to evaluate females since more women appear to be using these products. She suggested that it be tested in animal models of obesity, because these studies may reveal the mechanism by which mitochondrial pathways are modulated by steatatosis and because animals with fatty livers are more susceptible to hepatotoxicants.

Vincamine
The Board supported the recommendations for fundamental cardiotoxicity research studies. The NTP noted that studies with this compound would be integrated with the current QT interval prolongation research program.

General Discussion
Dr. Popp said the NTP should present clearly any exposure information on each nomination as these data impact the NTP's decision whether to study a compound or not. This is particularly relevant for dietary supplements. The Board said it is appropriate for the NTP to study dietary supplements and alternative medicines and suggested that the NTP coordinate with the NIH Office of Dietary Supplements in prioritizing these

substances for study. Dr. Allaben said dietary supplements are an area of emphasis for the FDA and the agency is coordinating these efforts closely with the NTP. Dr. Bucher said the NTP tries to focus its efforts on those compounds with the highest use and exposure and/or suspicion of human health hazard based on known pharmacological activity.

VI. Roadmap Activities

A. High Throughput Screening (HTS) assays
Dr. McQueen, a Board representative to the HTS Working Group (HTSWG), reported on a planning meeting held in June to discuss an NTP workshop on HTS. The objective of the workshop would be to educate the NTP about HTS assays, attempt to identify which assays might be the most appropriate for the NTP to adopt, and discuss the utility of this technology for the NTP and toxicology. At the planning meeting, the HTSWG outlined a preliminary agenda and identified proposed speakers. It was noted that additional details about the workshop would be announced in the Federal Register and posted on the NTP website.

Board Discussion
Dr. Daston said the needs of pharmaceutical companies for HTS would be different than those of the NTP. He suggested that the NTP include a member from the chemical industry on the HTSWG.

B. Nanotechnology Working Group
Dr. Roberts briefly summarized the public meeting of the NTP Board of Scientific Counselors Nanotechnology Working Group (NWG) held at the NIEHS on June 24, 2005. He said Dr. Clayton Teague, Director of the National Nanotechnology Coordination Office, made a presentation on the National Nanotechnology Initiative. His talk was followed by presentations by representatives from FDA, NIOSH, NIEHS, and NTP. Dr. Roberts identified some of the issues associated with nanotechnology – the infancy of the field, lack of a standard nomenclature, lack of knowledge about how best to conduct nanotoxicology studies and what quality controls to use. There was discussion regarding exposure in the workplace and how this should be addressed. He said FDA is studying the absorption and phototoxicity of nanomaterials that are added to cosmetics and other dermal products.

Board Discussion
Dr. Morandi suggested that the NTP include a chemist and a physicist as members of the NWG.

C. Workshop on Animal Models for the NTP Rodent Cancer Bioassay: Strains & Stocks - Should We Switch?

Dr. Angela King-Herbert, NIEHS, outlined the topics discussed at the workshop entitled "Animal Models for the NTP Rodent Cancer Bioassay: Strains & Stocks -- Should We Switch?" held on June 16 and 17, 2005 at the NIEHS. They included the currently used F344 rat stain, the currently used $B6C3F_1$ mouse strain, and the multiple strain approach. The workshop included plenary talks and three breakout groups to discuss these issues.

Dr. King Herbert summarized the recommendations from the three breakout groups.

- Rat Breakout Group: The NTP should discontinue use of the NTP F344 rat strain. There was some discussion about whether the NTP should use an inbred or outbred rat in the rodent bioassay. The use of the Wistar Han strain was discussed; however, it was not deemed suitable because it is insensitive to some chemicals.

- Mouse Breakout Group: This group agreed that the NTP $B6C3F_1$ strain is still useful although the background incidence of hepatic tumors has increased over the years. The group felt it is still possible to differentiate between the number of background tumors and those that arise due to chemical administration.

- Multiple Strain Breakout Group: Using a multiple strain approach for testing has the advantage of providing genetic variability and possibly increasing the statistical power. A drawback to this approach is that maximum tolerated doses would have to be established for each chemical in each strain used. The group noted that this could be very tough to accomplish logistically and would increase the cost of the study. The group recommended that any implementation of the multiple strain approach be done incrementally by addition of new strains over several years.

Dr. King-Herbert summarized the NTP's response to this input. The NTP would not change the current $B6C3F_1$ mouse model, but would develop another F344 rat stock and use a commercial strain in the interim. For the multiple strain approach, the NTP proposes to form a working group of the Board to investigate the cost, identify possible strains, and comment on whether it would be useful to determine the genetic make-up of each strain adopted.

Dr. Portier noted how pleased the NTP was with the workshop's thorough discussions and debate on these important topics. He said two topics for a future Board working group to address would be whether the NTP should target timing of exposure in the bioassay study such as animals during early, or animals in later life stages and whether genomics should be included routinely.

Board Discussion

Rats

Dr. Blair said the Brown Norway rat has a low background incidence of mononuclear cell leukemia and when crossed with the F344 strain, the F_1 has a lower incidence of leukemia than the parental F344 strain.

Mice

The Board agreed that the NTP should not change the $B6C3F_1$ mouse strain. The strain used at NIEHS is heavier than the strain used by NCTR scientists and the Board suggested that it might be useful to compare the genetic make-up of the two strains.

Multiple Strains

Dr. McQueen asked whether a genetic analysis has been undertaken on any of the suggested mouse strains because this information might be useful in deciding which strains to use. She asked if the NTP reviewed all the peer-reviewed publications using different strains, particularly as they pertain to pharmacokinetics. Dr. Daston said before the multiple strain recommendation is adopted, the NTP should (1) conduct a survey to establish whether the four selected strains with different genotypes respond differently, (2) whether the statistical power will be decreased or increased with the same total number of animals but spread out over a larger number of strains, and (3) what the differential cost of this type of study would be relative to a standard bioassay. The advantage of the present system with one strain is the strong statistical power that might be lost with multiple strains.

Dr. Roberts asked about the interpretation of a study if a chemical is positive in one strain and negative in another. Dr. Bucher said Dr. Grace Kissling, NIEHS, reported on a simulation of statistical data at the workshop. The simulation showed that the use of multiple stains would not have a major impact on the statistical power of a study. Dr. Boekelheide agreed that the use of three or four strains would not decrease the statistical power and it might lead to additional information on the mode of action of the chemical; however, the design of such a study would be more difficult and more costly. Dr. Portier said cost is an issue, as a dose range would have to be established for each strain and this extra effort would likely triple the cost of the pre-chronic studies.

Dr. Morandi approved the use of multiple strains on a selective basis because it would allow flexibility in the testing program. Dr. Blair liked the multiple strain approach; however, he said it still would not mimic the variability among humans. He said the thrust of using multiple stains should be on the identification of susceptible human populations. Dr. Birt was concerned about the interpretation of a study if positive data were found for only one of the multiple strains and asked whether the study would have to be repeated. However, she encouraged the NTP to design a study to "test the water."

Dr. Douglas Bristol, NIEHS, said studying 10 animals of 5 strains compared to 50 animals of one strain would address heterogeneity and would be more similar to the human condition. He believed the statistical power would increase with the multiple

strain approach. Dr. Bucher said the NTP would soon have haplotype maps and single nucleotide polymorphisms from an ongoing sequencing program of 15 mouse strains.

General Discussion

Dr. Popp summarized the discussion and said Dr. Portier has asked the Board for their opinion as to whether he should form a working group to further discuss the use of multiple strains. He said two topics for a future Board working group would be (1) whether the NTP should target timing of exposure in the bioassay such as only during neonatal or early life stages, or only during later life stages, and (2) whether genomics should be included routinely. The Board said there are three issues that need to be addressed: (1) the goal and objective of the bioassay program, (2) the advantages of using multiple strains in the testing program, and (3) whether alternate experimental designs should be added to the testing program. Several members agreed that another issue would be how to prioritize the different designs.

Instead of forming a working group to address these issues, Dr. Daston suggested that the NTP present to the Board a proposal on its priorities for the program and allow the Board to respond. Dr. McQueen seconded Dr. Daston's proposal. Dr. Portier said he would discuss this recommendation with his staff in the NTP and with the NTP's federal partners, and based on these discussions would decide whether to make a presentation at the next Board meeting on the role of the testing program in the context of the NTP's vision and strategic plan.

Dr. Portier thanked the Board members for attending the meeting and for their excellent suggestions and insight.

Agenda
NTP Board of Scientific Counselors Meeting

Rodbell Auditorium, Rall Building
National Institute of Environmental Health Sciences
Research Triangle Park, NC
August 18, 2005

8:30 AM	**Introductions**	Chair, Dr. James Popp, Stratoxon
8:40	**Welcome and Recognition of Retiring Members**	Dr. David Schwartz, NIEHS
9:00	**NIEHS/NTP Update** • Reporting NTP Studies • Public Comments • Board Discussion	Dr. Christopher Portier, NIEHS
9:30	**Peer Review Guidelines: Implications for the NTP** • Public Comments • Board Discussion	Dr. Mary Wolfe, NIEHS Dr. Christopher Portier, NIEHS
10:30	BREAK	
11:00	**Technical Reports Review Subcommittee** • Report on December 9, 2004 Meeting **(ACTION)** • Public Comments • Board Discussion • Upcoming Peer Review	Dr. Christopher Portier, NIEHS Dr. Stephen Roberts University of Florida Dr. David Malarkey, NIEHS
12:00 PM	LUNCH	
1:00	**NTP Study Nominations and ICCEC Recommendations** • Public Comments • Board Discussion	Dr. Scott Masten, NIEHS
2:30	BREAK	
3:00	**Roadmap Activities** • Planning Meeting for High Throughput Screening Workshop • Nanotechnology Public Meeting • Report on Workshop on "Animal Models for the NTP Rodent Bioassay: Strains and Stocks – Should We Switch?" • Public Comments • Board Discussion	Dr. Charlene McQueen, University of Arizona Dr. Stephen Roberts, University of Florida Dr. Angela King-Herbert, NIEHS
4:30	ADJOURN	

Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 9, 2005.

A. Federal Reserve Bank of Atlanta (Andre Anderson, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30303:

1. Omni Financial Services, Inc., Atlanta, Georgia; to acquire 100 percent of the voting shares of Georgia Community Bank, Dalton, Georgia, and thereby engage in operating a savings association, pursuant to section 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, May 10, 2005.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc.05–9730 Filed 5–13–05; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Liaison and Scientific Review Office (LSRO); Meeting of the NTP Board of Scientific Counselors

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

ACTION: Announcement of a meeting and request for comments.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors. The NTP Board of Scientific Counselors (NTP Board) is composed of scientists from the public and private sectors and provides primary scientific oversight to the Director for the NTP and evaluates the scientific merit of the NTP's intramural and collaborative programs.

DATES: The NTP Board meeting will be held on June 23, 2005. In order to facilitate planning for this meeting, persons wishing to make an oral presentation are asked to notify the Executive Secretary for the NTP Board by June 13, 2005 (*see* **FOR FURTHER INFORMATION CONTACT** below). Written comments should also be received by June 13, 2005, to enable review by the NTP Board and NIEHS/NTP staff prior to the meeting.

ADDRESSES: The NTP Board meeting will be held in the Rodbell Auditorium, Rall Building at the National Institute of Environmental Health Sciences, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709. A copy of the preliminary agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site (*http://ntp.niehs.nih.gov/* select "Advisory Boards and Committees") and provided upon request from the NTP (*see* **FOR FURTHER INFORMATION CONTACT** below).

FOR FURTHER INFORMATION CONTACT: Public comments and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP Board (NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–4253, fax: 919–541–0295; or e-mail: *shane@niehs.nih.gov*).

SUPPLEMENTARY INFORMATION: Primary agenda topics include: (1) An update of NTP activities including identification of two newly formed working groups of the NTP Board, the Nanotechnology Working Group (NWG) and the High Throughput Screening Working Group (HTSWG), (2) a summary of the June 16–17, 2005 workshop on "Animal Models for the NTP Rodent Cancer Bioassay: Strains and Stocks—Should We Switch?" (*see http://ntp.niehs.nih.gov/* select "Meetings and Workshops"), (3) testing recommendations for substances nominated to the NTP for study (*see http://ntp.niehs.nih.gov/* select "Nominations to the Testing Program"), (4) a report from the NTP Board's Technical Reports Review Subcommittee for the meeting held on December 9, 2004 (*see http://ntp.niehs.nih.gov/* select "Advisory Boards and Committees"), (5) implications of Office of Management and Budget peer review guidelines (**Federal Register**, Volume 70, Number 10, pages 2664–2677) for the NTP, and (6) a process to review NTP Briefs on reproductive hazards prepared by the NTP Center for the Evaluation of Risks to Human Reproduction. Time is allotted during the meeting for the public to present comment to the NTP Board and NTP staff on these agenda topics. Please note that this meeting provides a second opportunity for the public to provide comment on testing recommendations for substances nominated to the NTP. Comments submitted to the NTP in response to the May 5, 2005 **Federal Register** notice on this topic (**Federal Register**, Volume 70, Number 86, pages 23877–23880) will be considered at the Board meeting and do not need to be resubmitted.

Preliminary Agenda

NTP Board of Scientific Counselors—June 23, 2005. National Institute of Environmental Health Sciences Rodbell Auditorium, Rall Building 111 T.W. Alexander Drive Research Triangle Park, NC 27709; (A photo ID is required to access the NIEHS campus).

8:30 a.m.

- Call to Order and Introductions
- Welcome and Remarks from the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program (NTP)
- Update on NTP Activities

—Public Comment

- Report on the Workshop "Animal Models for the NTP Rodent Cancer Bioassay: Strains and Stocks—Should We Switch?"
- NTP Study Nominations and Recommendations

—Public Comment

12:30 p.m.
Lunch Break
1:30 p.m.

- NTP Board of Scientific Counselors Technical Reports Review Subcommittee

—Public Comment

- Office of Management and Budget Peer Review Guidelines: Implications for the NTP

—Public Comment

- Process for Peer Review of NTP Briefs from the Center for the Evaluation of Risks to Human Reproduction

—Public Comment

5 p.m.
Adjourn

Attendance and Registration

The meeting is scheduled for June 23, 2005, from 8:30 a.m. to adjournment and is open to the public with attendance limited only by the space available. Individuals who plan to attend are encouraged to register online at the NTP Web site by June 13, 2005, to facilitate access to the NIEHS campus. Please note that a photo ID is required to access the NIEHS campus. The NTP is making plans to videocast the meeting through the Internet at *http://www.niehs.nih.gov/external/video.htm*. Persons needing special assistance, such as sign language interpretation, or other reasonable accommodation in order to attend, are asked to notify the Executive Secretary for the NTP Board at least 7 business

days in advance of the meeting (*see* **FOR FURTHER INFORMATION CONTACT** above).

Availability of Meeting Materials

A copy of the preliminary agenda, committee roster, and any additional information, when available, will be posted on the NTP Web site or may be requested in hardcopy from the NTP Executive Secretary for the (*see* **FOR FURTHER INFORMATION CONTACT** above). Following the meeting, summary minutes will be prepared and made available on the NTP Web site.

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 comments will also be available on-site, although time allowed for presentation by on-site registrants may be less than that for pre-registered speakers and will be determined by the number of persons who register at the meeting.

Persons registering to make oral comments are asked, if possible, to send a copy of their statement to the Executive Secretary for the NTP Board (*see* **FOR FURTHER INFORMATION CONTACT** above) by June 13, 2005, to enable review by the NTP Board and NIEHS/NTP staff prior to the meeting. Written 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 to the NTP Board and NIEHS/NTP staff and to supplement the record. Written comments received in response to this notice will be posted on the NTP Web site. Persons submitting written comments should include their name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization (if any) with the document.

Background Information on the NTP Board of Scientific Counselors

The NTP Board is a technical advisory body comprised of scientists from the public and private sectors who provide primary scientific oversight to the overall program and its centers. Specifically, the NTP Board advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purposes of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields, such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology and neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. The NTP strives for equitable geographic distribution and minority and female representation on the NTP Board. Its members are invited to serve overlapping terms of up to four years. NTP Board meetings are held annually or biannually.

Dated: May 4, 2005.

Samuel H. Wilson,

Deputy Director, National Toxicology Program.

[FR Doc. 05–9625 Filed 5–13–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

OCS; Notice of Correction for the CCF Demonstration Program Announcement

AGENCY: Office of Community Services, ACF, HHS.

ACTION: Notice of Correction.

FUNDING OPPORTUNITY TITLE: Demonstration Program.

FUNDING OPPORTUNITY NUMBER: HHS–2005–ACF–OCS–EJ–0035.

SUMMARY: This notice is to inform interested parties of corrections made to the CCF Demonstration Program published on Friday, April 29, 2005. The following corrections should be noted:

Under IV.6 Other Submission Requirements, the correct address to mail and hand deliver applications is: U.S. Department of Health and Human Services (HHS), Attention: Eduardo Hernandez, Administration for Children and Families Office of Community Services, Operations Center, Compassion Capital Fund Demonstration Program, 1515 Wilson Boulevard, Suite 100, Arlington, Virginia 22209. Phone: 1–800–281–9519. E-mail: *OCS@lcgnet.com.*

The only changes to the CCF Demonstration Program Announcement are explicitly stated in this Notice of Correction. All applications must still be sent on or before the deadline date of June 13, 2005.

For further information contact the OCS Grants Operations Center at the above phone number or address.

Dated: May 9, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–9694 Filed 5–13–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Community Services: Notice of Correction for the CCF Targeted Capacity Building Program Announcement

AGENCY: Office of Community Services, ACF, DHHS.

ACTION: Notice of correction.

Funding Opportunity Title: Targeted Capacity Building Program.

Funding Opportunity Number: HHS–2005–ACF–OCS–IJ–0036.

SUMMARY: This notice is to inform interested parties of corrections made to the CCF Targeted Capacity Building Program published on Friday, April 29, 2005. The following corrections should be noted:

Under IV.6 Other Submission Requirements, the correct address to mail and hand deliver applications is: U.S. Department of Health and Human Services (HHS), Attention: Eduardo Hernandez, Administration for Children and Families Office of Community Services, Operations Center, Compassion Capital Fund Targeted Capacity Building Program, 1515 Wilson Boulevard, Suite 100, Arlington, Virginia 22209, Phone: 1–800–281–9519, E-mail: *OCS@lcgnet.com.*

The only changes to the CCF Targeted Capacity Building Program Announcement are explicitly stated in this Notice of Correction. All applications must still be sent on or before the deadline date of May 31, 2005.

FOR FURTHER INFORMATION CONTACT: The OCS Grants Operations Center at the Above Phone Number or Address.

Dated: May 9, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–9693 Filed 5–13–05; 8:45 am]

BILLING CODE 4184–01–P

proposed paperwork collections referenced above, access the HHS Web site address at *http://www.hhs.gov/oirm/infocollect/pending/* or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to *naomi.cook@hhs.gov*, or call the Reports Clearance Office on (202) 690–6162. Written comments and recommendations for the proposed information collections must be mailed directly to the Desk Officer at the address below: OMB Desk Officer: Katherine Astrich, OMB Human Resources and Housing Branch, Attention: (OMB#OS–4040–0002), New Executive Office Building, Room 10235, Washington DC 20201.

Dated: June 23, 2005.

Robert E. Polson,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 05–13078 Filed 6–30–05; 8:45 am]

BILLING CODE 4168–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); Liaison and Scientific Review Office (LSRO); NTP Board of Scientific Counselors Meeting Rescheduled

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

ACTION: Meeting announcement.

SUMMARY: Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Toxicology Program (NTP) Board of Scientific Counselors. Please be advised that the NTP Board of Scientific Counselors meeting originally scheduled for June 23, 2005, as published in the **Federal Register** (Vol. 80, No. 93 pp. 25830–25831) on May 16, 2005 is postponed to August 18, 2005. The tentative agenda published in the May 16 notice and the guidelines for submitting public comments or making an oral presentation at the meeting still apply. Any updates to the agenda or additional information and background materials will be posted on the NTP Web site (*http://ntp.niehs.nih.gov/* select "Advisory Boards and Committees") and provided upon request from the NTP (see **FOR FURTHER INFORMATION CONTACT** below).

DATES: The date for receiving public comments has been extended. Written comments should be received by August 8, 2005, to enable review by the NTP Board and NIEHS/NTP staff prior to the meeting. In order to facilitate planning for this meeting, persons wishing to make an oral presentation on any agenda topic are asked to notify the Executive Secretary for the NTP Board by August 8, 2005 (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.

FOR FURTHER INFORMATION CONTACT: Public comments and any other correspondence should be submitted to Dr. Barbara Shane, Executive Secretary for the NTP Board (NTP Liaison and Scientific Review Office, NIEHS, P.O. Box 12233, MD A3–01, Research Triangle Park, NC 27709; telephone: 919–541–4253, fax: 919–541–0295; or e-mail: *shane@niehs.nih.gov*).

Dated: June 21, 2005.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 05–12972 Filed 6–30–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Revised Privacy Act System of Records

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of a revised Privacy Act system of records.

SUMMARY: The Department of Health and Human Services (HHS) is publishing a notice of a revised system of records, 09–90–0024, "Unified Financial Management System, HHS/OS" which was published in the **Federal Register** on September 7, 1999. The revised notice changes the system name from "09–90–0024, Financial Transactions of HHS Accounting and Finance Offices" to "09–90–0024, Unified Financial Management System" to meet the needs of the newly-established Unified Financial Management System (UFMS), and update Agency information.

DATES: The revised system notice is effective 30 days after the date of publication, unless HHS receives comments which would result in a contrary determination.

ADDRESSES: Mail public comments to Ms. Dara Murray, Chief Information Security Officer, Program Support Center, 5600 Fishers Lane, Room 17A30, Rockville, MD 20857. Telephone 301–443–0881. This is not a toll-free number. Comments will be available for public inspection and copying at the above location.

FOR FURTHER INFORMATION CONTACT: Chief Information Security Officer, Program Support Center, 5600 Fishers Lane, Room 17A30, Rockville, MD 20857, (301) 443–0881.

Dated: June 10, 2005.

Kerry Weems,

Principal Deputy Assistant Secretary, for Budget, Technology and Finance, Office of the Secretary.

09–90–0024

SYSTEM NAME:

Unified Financial Management System, HHS/OS.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

See Appendix 1.

Memoranda copies of claims submitted for reimbursement of travel and other expenditures while on official business may also be maintained at the administrative and/or program office of the HHS employee. Records concerning outstanding debts may also be maintained at the program office or by the designated claims officer apart from the finance office.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All persons who receive a payment from the Operating Divisions (OPDIV) Headquarters, Area and District offices, and all persons owing monies to these HHS components. Persons receiving payments include, but are not limited to travelers on official business, grantees, contractors, consultants, Fellows and recipients of loans and scholarships, and also employee reimbursement for training classes, mass transit, and other appropriate costs. Persons owing monies include, but are not limited to, persons who have been overpaid and who owe HHS a refund and persons who have received from HHS goods or services for which there is a charge or fee (*e.g.*, Freedom of Information Act requesters).

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, identification number/Social Security Number (SSN) or EIN/TID, address, e-mail address, phone number, purpose of payment or request for payment bank account and routing numbers, accounting classification and the amount paid of billed. Also, in the event of an overpayment and for outstanding charges, fees, loans, grants or scholarships, the amount of the indebtedness, the repayment status and the amount to be collected.

NATIONAL TOXICOLOGY PROGRAM
Board of Scientific Counselors Meeting
August 18, 2005

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Charlene A. McQueen, Ph.D.
Professor
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NATIONAL TOXICOLOGY PROGRAM
Board of Scientific Counselors Meeting
August 18, 2005

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Mary Vore, Ph.D.
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Cheryl Lyn Walker, Ph.D. ***
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Bruce S. Weir, Ph.D.
William Neal Reynolds Professor of Statistics
and Genetics
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ad hoc
Kim Boekelheide, M.D., Ph.D.
Professor, Division of Biology and Medicine
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*** not in attendance