signed Confidential Disclosure Agreement will be required to receive a copy of any pending patent applications.

SUPPLEMENTARY INFORMATION: Gaucher Disease is a rare inborn error of metabolism which affects between 10,000 and 20,000 people worldwide, 40% in the United States. Gaucher Disease is the most common lipid storage disease. The symptoms associated with Gaucher Disease result from the accumulation of a lipid called glucocerebroside. This lipid is a byproduct of the normal recycling of red blood cells. When the gene with the instructions for producing an enzyme to break down this byproduct is defective, the lipid accumulates. The lipid is found in many places in the body, but most commonly in the macrophages in the bone marrow. There it interferes with normal bone marrow functions, such as production of platelets (leading to bleeding and bruising) and red blood cells (leading to anemia) and potentially death. The presence of glucocerebroside seems to also trigger the loss of minerals in the bones, causing the bones to weaken, and can interfere with the bone's blood supply.

The field of use is directed to the development of therapies for remedying enzyme deficiencies in the treatment of Gaucher Disease.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within ninety (90) days from the date of this published notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 11, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer.

[FR Doc. 00–24241 Filed 9–20–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), National Toxicology Program (NTP); Notice of an International Workshop on *In Vitro* Methods for Assessing Acute Systemic Toxicity, co-sponsored by NIEHS, NTP and the U.S. Environmental Protection Agency (EPA): Workshop Agenda and Registration Information

SUMMARY: Pursuant to Public Law 103–43, notice is hereby given of a public meeting sponsored by NIEHS, the NTP, and the EPA, and coordinated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM). The agenda topic is a scientific workshop to assess the current status of *in vitro* test methods for evaluating the acute systemic toxicity potential of chemicals and to develop recommendations for future research, development, and validation studies. The workshop will take place on October 17–20, 2000, at the Hyatt Regency Crystal City Hotel, 2799 Jefferson Davis Highway, Arlington, VA, 22202. The meeting will be open to the public.

In a previous **Federal Register** notice (Vol. 65, No. 115, pp. 37400–37403), ICCVAM requested information and data that should be considered at the Workshop and nominations of expert scientists to participate in the Workshop. A preliminary list of relevant studies to be considered for the Workshop was also provided. As a result of this request, an ICCVAM interagency Workshop Organizing Committee has selected an international group of scientific experts to participate in this Workshop. NICEATM, in collaboration with ICCVAM, has developed a background summary of data and performance characteristics for available *in vitro* methods. This summary will be made available to invited expert scientists and the public before the Workshop. Requests for the summary can be made to the address given below. This notice provides an agenda, registration information, and updated details about the Workshop.

Workshop Background and Scope

A. Background

Acute toxicity testing is conducted to determine the hazards of various chemicals and products. This information is used to properly classify and label materials as to their lethality in accordance with an internationally harmonized system (OECD, 1998). Non-lethal endpoints may also be evaluated to identify potential target organ toxicity, toxicokinetic parameters, and dose-response relationships. While animals are currently used to evaluate acute toxicity, recent studies suggest that *in vitro* methods may also be helpful in predicting acute toxicity.

Studies by Spielmann *et al.* (1999) suggest that *in vitro* cytotoxicity methods may be useful in predicting a starting dose for *in vivo* studies, and thus may potentially reduce the number of animals necessary for such determinations. Other studies (*e.g.,* Ekwall *et al.,* 2000) have indicated an association between chemical concentrations leading to *in vitro* cytotoxicity and human lethal blood concentrations. A program to assess toxicokinetics and target organ toxicity utilizing *in vitro* methods has been proposed that may provide enhanced predictions of toxicity and potentially reduce or replace animal use for some tests (Ekwall *et al.,* 1999). However, many of the necessary *in vitro* methods for this program have not yet been developed. Other methods have not been evaluated in validation studies to determine their usefulness and limitations for generating information to meet regulatory requirements for acute toxicity testing. Development and validation of *in vitro* methods which can establish accurate dose-response relationships will be necessary before such methods can be considered for the reduction or replacement of animal use for acute toxicity determinations.

This workshop will examine the status of available *in vitro* methods for assessing acute toxicity. This includes screening methods for acute toxicity, such as methods that may be used to predict the starting dose for *in vivo* animal studies, and methods for generating information on toxicokinetics, target organ toxicity, and mechanisms of toxicity. The workshop will develop recommendations for validation efforts necessary to characterize the usefulness and limitations of these methods. Recommendations will also be developed for future mechanism-based research and development efforts that might further improve *in vitro* assessments of acute systemic lethal and non-lethal toxicity.

B. Objectives of the Workshop

Four major topics will be addressed:

- *In Vitro* Screening Methods for Assessing Acute Toxicity;

• *In Vitro* Methods for Toxicokinetic Determinations;
• *In Vitro* Methods for Predicting Organ Specific Toxicity; and
• Chemical Data Sets for Validation of *In Vitro* Acute Toxicity Test Methods.

The objectives of the meeting are to:

1. Review the status of *in vitro* methods for assessing acute systemic toxicity:

a. Review the validation status of available *in vitro* screening methods for their usefulness in estimating *in vivo* acute toxicity,

b. Review *in vitro* methods for predicting toxicokinetic parameters important to acute toxicity (*i.e.,* absorption, distribution, metabolism, elimination), and

c. Review *in vitro* methods for predicting specific target organ toxicity;

2. Recommend candidate methods for further evaluation in prevalidation and validation studies;

3. Recommend validation study designs that can be used to characterize adequately the usefulness and limitations of proposed *in vitro* methods;

4. Identify reference chemicals that can be used for development and validation of *in vitro* methods for assessing *in vivo* acute toxicity; and

5. Identify priority research efforts necessary to support the development of mechanism-based *in vitro* methods to assess acute systemic toxicity. Such efforts might include incorporation and evaluation of new technologies, such as gene microarrays, and development of methods necessary to generate dose response information.

Workshop Information

A. Workshop Agenda

Tuesday, October 17, 2000

8:30 a.m.—Opening Plenary Session
• Workshop Introduction
• Welcome from the National Toxicology Program (NTP)
• Overview of ICCVAM and NICEATM
• Acute Toxicity: Historical and Current Regulatory Perspectives
• Acute Toxicity Data: A Clinical Perspective

10:30 a.m.—*In Vitro* Approaches to Estimate the Acute Toxicity Potential of Chemicals
• Estimating Starting Doses for *In Vivo* Studies using *In Vitro* Data
• An Integrated Approach for Predicting Systemic Toxicity
• Opportunities for Future Progress
Public Comment
Breakout Groups' Charges
12:30 p.m.—Lunch Break

1:45 p.m.—Breakout Groups: Identifying What Is Needed from *In Vitro* Methods
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
5:30 p.m.—Adjourn for the Day

Wednesday, October 18, 2000

8:00 a.m.—Plenary Session—Status Reports by Breakout Group Co-Chairs
9:00 a.m.—Breakout Groups: Current Status of *In Vitro* Methods for Acute Toxicity
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
12:00 p.m.—Lunch Break
1:30 p.m.—Breakout Groups: Current Status of *In Vitro* Methods for Acute Toxicity (Cont'd)
5:30 p.m.—Adjourn for the Day

Thursday, October 19, 2000

8:00 a.m.—Plenary Session—Status Reports by Breakout Group Co-Chairs
9:00 a.m.—Breakout Groups: Future Directions for *In Vitro* Methods for Acute Toxicity
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
12:00 p.m.—Lunch Break
1:30 p.m.—Breakout Groups: Future Directions for *In Vitro* Methods for Acute Toxicity (Cont'd)
5:30 p.m.—Adjourn for the Day

Friday, October 20, 2000

8:00 a.m.—Closing Plenary Session—Reports by Breakout Group Co-Chairs
• Screening Methods;
• Toxicokinetic Determinations;
• Predicting Organ Specific Toxicity and Mechanisms; and
• Chemical Data Sets for Validation
Public Comment
Closing Comments
12:15 p.m.—Adjourn

B. Workshop Registration

The Workshop meeting will be open to the public, limited only by the space available. Due to space limitations, advance registration is requested by October 13, 2000. Registration forms can be obtained by contacting NICEATM at the address given below or by accessing the on-line registration form at: *http://iccvam.niehs.nih.gov/invi_reg.htm.* Other relevant Workshop information (*i.e.,* accommodations, transportation, etc.) is also provided at this website.

C. Public Comment

The Public is invited to attend the Workshop and the number of observers will be limited only by the space available. Two formal public comment sessions on Tuesday, October 17th and Friday, October 20th will provide an opportunity for interested persons or groups to present their views and comments to the Workshop participants (please limit to one speaker per group). Additionally, time will be allotted during each of the Breakout Group sessions for general discussion and comments from observers and other participants. The Public is invited to present oral comments or to submit comments in writing for distribution to the Breakout Groups to NICEATM at the address given below by October 13, 2000. Oral presentations will be limited to seven minutes per speaker to allow for a maximum number of presentations. Individuals presenting oral comments are asked to provide a hard copy of their statement at registration. For planning purposes, persons wishing to give oral comments are asked to check the box provided on the Registration Form, although requests for oral presentations will also be accepted on-site (subject to availability of time). Persons registering for oral comments or submitting written remarks are asked to include their contact information (name, address, affiliation, telephone, fax, and e-mail).

Guidelines for Requesting Registration Form and Submission of Public Comment

Requests for registration information and submission of public comments should be directed to the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods, Environmental Toxicology Program, NIEHS/NTP, MD EC–17, PO Box 12233, Research Triangle Park, NC 27709; 919–541–3398 (phone); 919–541–0947 (fax); *iccvam@niehs.nih.gov* (e-mail). Public comments should be accompanied by complete contact information including name, (affiliation, if applicable), address, telephone number, and e-mail address.

References

• OECD (Organisation for Economic Cooperation and Development). (1998). Harmonized integrated hazard classification system for human health and environmental effects of chemical substances. OECD, Paris. (website: *http://www.oecd.org//ehs/Class/HCL6.HTM*)
• Spielmann, H., Genschow, E., Leibsch, M., and Halle, W. (1999) Determination of the starting dose for

acute oral toxicity (LD50) testing in the up and down procedure (UDP) from cytotoxicity data. ATLA, 27(6), 957–966.

• Ekwall, B., Ekwall, B., and Sjorstrom, M. (2000) MEIC evaluation of acute systemic toxicity: Part VIII. Multivariate partial least squares evaluation, including the selection of a battery of cell line tests with a good prediction of human acute lethal peak blood concentrations for 50 chemicals. ATLA, 28, Suppl. 1, 201–234.

• Ekwall, B., Clemedson, C., Ekwall, B., Ring, P., and Romert, L. (1999) EDIT: A new international multicentre programme to develop and evaluate batteries of *in vitro* tests for acute and chronic systemic toxicity. ATLA 27, 339–349.

Dated: September 12, 2000.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 00–24244 Filed 9–20–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4463–N–04]

Notice of FHA Debenture Call

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This Notice announces a debenture recall of certain Federal Housing Administration debentures, in accordance with authority provided in the National Housing Act.

FOR FURTHER INFORMATION CONTACT: Richard Keyser, Room 3119P, L'Enfant Plaza, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410, telephone (202) 755–7510 x137. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Pursuant to Sections 204(c) and 207(j) of the National Housing Act, 12 U.S.C. 1710(c), 1713(j), and in accordance with HUD's regulation at 24 CFR 203.409 and § 207.259(e)(3), the Federal Housing Commissioner, with approval of the Secretary of the Treasury, announces the call of all Federal Housing Administration debentures, with a coupon rate of 6.625 percent or above, except for those debentures subject to ''debenture lock agreements'', that have been registered on the books of the Federal Reserve Bank of Philadelphia, and are, therefore, ''outstanding'' as of September 30, 2000. The date of the call is January 1, 2001.

The debentures will be redeemed at par plus accrued interest. Interest will cease to accrue on the debentures as of the call date. Final interest on any called debentures will be paid with the principal at redemption.

During the period from the date of this notice to the call date, debentures that are subject to the call may not be used by the mortgagee for a special redemption purchase in payment of a mortgage insurance premium.

No transfer of debentures covered by the foregoing call will be made on the books maintained by the Treasury Department on or after October 1, 2000. This does not affect the right of the holder of a debenture to sell or assign the debenture on or after this date. Payment of final principal and interest due on January 1, 2001, will be made automatically to the registered holder.

Dated: September 15, 2000.

William C. Apgar,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 00–24288 Filed 9–20–00; 8:45 am]

BILLING CODE 4210–27–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–841026

Applicant: Thane Wibbels, University of Alabama at Birmingham, Birmingham, AL

The applicant requests a permit to import up to 1000 blood samples and up to 500 tissue samples taken from Kemp's Ridley sea turtles (*Lepidochelys kempii*) in Mexico for enhancement of the species through scientific research. This notification covers activities conducted by the applicant over a five year period.

PRT–032758

Applicant: Exotic Feline Breeding Compound, Inc., Rosamond, CA

The applicant requests a permit to import 1 captive-born male Amur leopard (*Panthera pardus orientalis*) from the Novosibirsk Zoo, Russia for the purpose of propagation for the enhancement of the survival of the species.

PRT–032757

Applicant: Omaha's Henry Doorly Zoo, Omaha, NE

The applicant requests a permit to import 1 captive-born female Sumatran tiger (*Panthera tigris sumatrae*) from the Surabaya Zoo, Indonesia for the purpose of propagation for the enhancement of the survival of the species.

PRT–031061

Applicant: Susan E. Aronoff, Tampa, FL, 33624

The applicant requests a permit to import 1 captive-born male cheetah (*Acinonyx jubatus*) from the Endangered Animal Foundation, Driftweg, the Netherlands to enhance the survival of the species through conservation education.

PRT–830414

Applicant: Duke University Primate Center, Durham, NC

The applicant requests re-issuance of a permit to import two male and three female wild-caught golden-crowned sifakas (*Propithecus tattersalli*) from Dariana, Madagascar for the purpose of propagation for the enhancement of the survival of the species. This notification covers requests for re-issuances of the permit by the applicant over a five year period.

PRT–808256

Applicant: Duke University Primate Center, Durham, NC

The applicant requests re-issuance of a permit to import one male and two female wild-caught diademed sifakas (*Propithecus diadema*) from the Department of Water and Forest, Maramize, Madagascar for the purpose of propagation for the enhancement of the survival of the species. This notification covers requests for re-issuances of the permit by the applicant over a five year period.

PRT–031796

Applicant: Larry Edward Johnson, Boerne, TX

The applicant requests a permit to export two male and two female captive-born ring-tailed lemurs (*Catta lemur*) to Munchi's Zoo, Buenos Aires, Argentina to enhance the survival of the species through conservation education and captive propagation.

PRT–026102

Applicant: Elizabeth G. Stone/University of Georgia, Athens, GA

The applicant requests a permit to import salvaged specimens, non-viable eggs, and biological samples from Thick-billed parrots (*Rhynchopsitta pachyrhyncha*) collected in the wild in Mexico, for scientific research. This