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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Data and Information on Technologies Used for Identifying Potential Developmental Toxicants

SUMMARY: The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for identifying potential developmental toxicants. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the potential of chemicals to induce adverse effects in offspring.

DATES:

Receipt of information: Deadline is [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Warren Casey, Director, NICEATM;
email: warren.casey@nih.gov; telephone: (919) 316-4729.

SUPPLEMENTARY INFORMATION:

Background: NICEATM, which fosters the evaluation and promotion of alternative test methods for regulatory use, is supporting efforts to develop, validate, and implement alternative approaches for identifying potential developmental toxicants. The goal of these alternative approaches is to replace, reduce, or refine the use of animals in testing. Testing a chemical's potential to cause developmental toxicity is required by multiple regulatory agencies and may require the use of large numbers of animals.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to identify potential developmental toxicants. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo developmental toxicity test methods currently required by regulatory agencies, including data from non-animal chemical tests for developmental hazard potential. NICEATM also requests any available data resulting from in vivo developmental studies, ethical human or animal studies, or accidental human exposures, using the same chemicals.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL

REGISTER]. Responses to this notice will be posted at: <http://ntp.niehs.nih.gov/go/dev-nonanimal>. Persons submitting responses will be identified on the Web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) provides authority for ICCVAM and NICEATM in the development of alternative test methods. Information about NICEATM and ICCVAM is found at <http://ntp.niehs.nih.gov/go/niceatm> and <http://ntp.niehs.nih.gov/go/iccvam>.

Dated: June 24, 2016

John R. Bucher,
Associate Director, National Toxicology Program

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