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DATE: February 23, 2004

TO: Scientific Advisory Committee on Alternative Toxicological
Methods (SACATM)

FROM: Director, NTP Interagency Center for the Evaluation
of Alternative Toxicological Methods (NICEATM)
and Chairman, Interagency Coordinating Committee on the
Validation of Alternative Toxicological Methods (ICCVAM)

SUBJECT: ICCVAM Guidelines for the Nomination and Submission of
New, Revised, and Alternative Test Methods

On behalf of the ICCVAM, we are pleased to provide you with the recently published "ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods," NIH Publication No. 03-4508 (Attachment 1). This document is the second revision to guidelines originally published in 1998. It provides updated guidance to test method sponsors and nominators on the information needed by ICCVAM to evaluate the validation status of new or revised test methods at any stage of development and after the completion of validation studies. It also includes a framework for organizing information supporting the validity of a test method.

New additions to this document include a chapter on the ICCVAM test method nomination and submission process, and a chapter on performance standards for test methods.

Availability of this publication was announced in a *Federal Register* notice on Friday, November 14, 2003, (68 FR 64636; Attachment 2). We would also appreciate your assistance in further dissemination of this document to interested stakeholders. Copies can be requested from NICEATM (919-541-2384 or by email: niceatm@niehs.nih.gov), or the document can also be accessed via the Internet at: <http://iccvam.niehs.nih.gov/docs/guidelines/subguide.htm>.

We also welcome your suggestions for improving the usefulness of these guidelines at any time. These will be used to update a future revised version.

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Attachments (2)