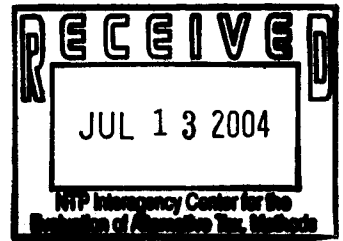




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



JUN 21 2004

OFFICE OF PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
OFFICE OF PESTICIDE PROGRAMS
(7501C)

James J. Jones, Director

William S. Stokes, D.V.M., Diplomate ACLAM
Director, National Toxicology Program Interagency Center for
the Evaluation of Alternative Toxicological Methods
Environmental Toxicology Program
National Institute of Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. Stokes:

The U.S. Environmental Protection Agency (EPA/the Agency) is working to develop a non-animal assessment approach for evaluating the skin and eye irritation potential and labeling requirements for antimicrobial cleaning product formulations. To that end, EPA's Office of Pesticide Programs (OPP) is planning for a technical workshop under the auspices of its Pesticide Program Dialogue Committee (PPDC) along with PPDC members Troy Seidle (People for the Ethical Treatment of Animals), Len Sauers (Proctor and Gamble), and Pat Quinn (Accord Group). Other participants in this technical workshop and the development of a non-animal assessment approach include, but are not limited to, representatives of the Institute for In-Vitro Sciences (IIVS) of Gaithersburg, MD, and S.C. Johnson & Sons, Inc.

The Agency recognizes the importance of identifying scientifically sound alternative test methods that have the potential to reduce, refine or replace animal usage. Given that a primary responsibility of the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is to shepherd the processes involved in assessing the validation status of test methods which have been recommended or nominated for consideration, EPA is interested in engaging your participation in this process/project.

Current plans for this project call for the following activities to be undertaken over the next year or so:

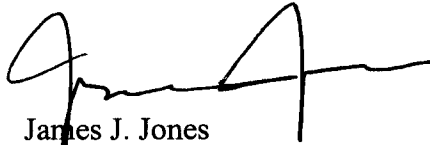
- ✓Data collection and preparation of background materials (Summer 2004);
- ✓Presentation of workshop proposal to the PPDC (at Fall 2004 meeting);
- ✓Open/public technical workshop to be held by the Agency (early in 2005);

- ✓Presentation of workshop summary and recommendations to PPDC (Spring 2005);
- ✓Consideration (by the Agency, based upon outcome of the workshop and PPDC advice) of setting interim policy for acceptance of non-animal tests to determine skin and eye irritation labeling for antibacterial cleaning products in defined product categories (Spring 2005);
- ✓Technical review, by ICCVAM, of workshop recommendations and interim policy (if adopted) (Summer 2005);
- ✓Science Advisory Panel (SAP) guideline amendment (Fall 2005); and,
- ✓Full implementation (Fall 2005).

We are aware that this project will call for your (and perhaps others in NICEATM) services at various points over the next year; and, are willing to assist with funding for this project, subject to Agency budget allocations. Please contact Jack Housenger, Associate Director of OPP's Antimicrobials Division (AD) or Tina Levine, Director of OPP's Benefits and Economic Analysis Division (BEAD) if you have any questions regarding this project and/or to confirm your willingness to participate, at your earliest convenience. Jack can be reached by phone on 703-308-6411 or by email at: housenger.jack@epa.gov; and Tina can be reached by phone on 703-308-3099 or by email at: levine.tina@epa.gov.

Thank you, in advance, for your consideration and participation in this important effort.

Sincerely,



James J. Jones
Director

cc: Margie Fehrenbach
Jack Housenger
Tina Levine
Debra Edwards
Frank Sanders
Lois Rossi
Deborah McCall
Joseph Merenda