

Subject: BELIEVE THIS IS FAR TOO LITTLE - AM NOT SATISFIED WITH PROGRESS IN STOPPING ABUSE OF ANIMALS.

Date: Friday, June 15, 2012 10:40:21 AM ET

From: usacitizen1 usacitizen1

To: NIEHS NICEATM, [REDACTED]
[REDACTED]

CC: [REDACTED]
[REDACTED]

I BELIEVE THIS REPORT SHOWS FAR FAR TOO LITTLE PROGRESS IN STOPPING THE ABUSE OF ANIMALS IN LAB TESTS. I WANT MORE PROGRESS THAN THIS. I DO NOT SEE WHY WE ARE USING ANIMALS FOR THESE TESTS SINCE THAT WAS A PROCESS STARTED IN 1500 A.D. THIS IS 2012. YOU HAVE NOT MADE MUCH PROGRESS TO CONTINUE ABUSING ANIMALS AS YOU ARE. LOOK AT THE NIM FILM WHY DON'T YOU. THIS COMMENT IS FOR THE PUBLIC RECORD. JEAN PUBLIC

2010–2011 HIGHLIGHTS

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) was established in 1997 to conduct interagency technical evaluations of new safety testing methods, including alternative testing methods that will reduce, refine (enhance animal well-being and lessen or avoid pain and distress), and replace the use of animals. ICCVAM was also established to coordinate cross-agency activities relating to development, validation, acceptance, and national and international harmonization of new, modified, and alternative toxicological test methods.

The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), ICCVAM, and the ICCVAM member agencies have contributed to the evaluation of 50 alternative methods that have been approved or endorsed by Federal regulatory agencies and international test guideline organizations. Of these, 33 are

in vitro methods that reduce or replace animal use. The other 17 are *in vivo* methods that significantly reduce the number of animals used or significantly improve animal welfare by minimizing or avoiding potential pain and distress.

This report describes test method evaluations and other activities that ICCVAM conducted in 2010 and 2011 in conjunction with NICEATM. Selected highlights follow.

Eye Safety Testing

- In 2010, ICCVAM recommended alternative methods and strategies to reduce animal use and to minimize or avoid unrelieved pain and distress during eye safety testing. Federal agencies accepted or endorsed ICCVAM recommendations for the following alternative methods in 2011:
 - Pain management procedures that should always be used to avoid or minimize unrelieved pain and distress when *in vitro* methods do not provide sufficient eye safety information and it is necessary to use animals to meet regulatory safety testing requirements. These procedures include the routine use of topical anesthetics, systemic analgesics, and earlier humane endpoints.
 - An *in vitro* Cytosensor microphysiometer (CM) test method that can be used as a screening test to identify some types of substances that may cause permanent or severe eye injuries and to determine if some types of substances will not cause sufficient injury to require hazard labeling for

eye irritation. *The CM test method is the first accepted in vitro test method that can be used instead of animals to identify substances that do not require eye hazard labeling.*

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–Reports on the current validation status of four *in vitro* test methods for identifying substances with the potential to cause nonsevere ocular injuries, and recommended studies to further characterize their usefulness and limitations.

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–Reports on the current validation status and recommended additional studies for a non-animal *in vitro* testing strategy proposed to assess the eye irritation potential of antimicrobial cleaning products using the bovine corneal opacity and permeability (BCOP), CM, and EpiOcular™ (MatTek) test methods. The recommended studies will provide data necessary to support evaluation of the usefulness and limitations of the proposed testing strategy.

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–A report on the validation status of the low volume rabbit eye test, and recommendations that it should not be used for prospective *in vivo* ocular safety testing due to performance issues.

- NICEATM and ICCVAM developed draft eye injury hazard classification criteria to support consumer product safety testing with 3 animals rather than the current 6 to 18 animals. The recommended classification criteria provide the same or greater level of eye injury hazard labeling as current requirements, while using 50% to 83% fewer animals.

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- > [Federal Register Volume 77, Number 114 (Wednesday, June 13, 2012)]
- > [Notices]
- > [Pages 35393-35394]
- > From the Federal Register Online via the Government Printing Office
- > [www.gpo.gov]
- > [FR Doc No: 2012-14436]

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> DEPARTMENT OF HEALTH AND HUMAN SERVICES

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> Biennial Progress Report of the Interagency Coordinating
> Committee on the Validation of Alternative Methods (ICCVAM)

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> AGENCY: Division of the National Toxicology Program (DNTP), National
> Institute of Environmental Health Sciences (NIEHS), National Institutes
> of Health (NIH).

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> ACTION: Availability of Report.

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> SUMMARY: The NTP Interagency Center for the Evaluation of Alternative

- > Toxicological Methods (NICEATM) announces the availability of the
- > Biennial Progress Report 2010-2011: Interagency Coordinating Committee
- > on the Validation of Alternative Methods. The report was prepared in
- > accordance with requirements of the ICCVAM Authorization Act of 2000
- > (42 U.S.C. 285I-3).
- > The Biennial Progress Report describes activities and progress by
- > NICEATM and ICCVAM during the period from January 2010 through December
- > 2011. During the past two years, NICEATM, ICCVAM, and ICCVAM member
- > agencies contributed to the national and international endorsement and
- > adoption of 14 new and updated alternative safety testing methods.
- > Since ICCVAM was established, NICEATM, ICCVAM, and the ICCVAM member
- > agencies have contributed to the regulatory acceptance of over 50
- > alternative methods that can be used to protect the health of people,
- > animals, and the environment while reducing, refining, and replacing
- > animal use.
- > The Biennial Progress Report is available on the NICEATM-ICCVAM Web
- > site at <http://iccvam.niehs.nih.gov/about/ICCVAMrpts.htm>. Copies can
- > also be requested from NICEATM (see ``ADDRESSES").
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- > ADDRESSES: Requests for copies of the report should be sent by mail,
- > fax, or email to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O.
- > Box 12233, Mail Stop: K2-16, Research Triangle Park, NC 27709,
- > (telephone) 919-541-2384, (fax) 919-541-0947, (email)
- > niceatm@niehs.nih.gov. Courier address: NICEATM, NIEHS, Room 2034, 530
- > Davis Drive, Morrisville, NC 27560.
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- > FOR FURTHER INFORMATION CONTACT: Dr. William S. Stokes, NICEATM
- > Director (phone 919-541-2384 or niceatm@niehs.nih.gov).
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- > SUPPLEMENTARY INFORMATION:
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- > Background
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- > The ICCVAM Authorization Act of 2000 established ICCVAM as a
- > permanent interagency committee of NIEHS under NICEATM. The Act directs
- > ICCVAM to coordinate interagency technical reviews of proposed new,
- > revised, and alternative testing methods, including those that may
- > reduce, refine (enhance animal well-being and lessen or avoid pain and
- > distress), and replace animal use. ICCVAM prepares test method
- > recommendations based on their scientific validity for regulatory
- > safety testing, and submits these recommendations through the HHS
- > Secretary (or designee) to U.S. Federal Agencies for adoption
- > decisions.
- > A provision of the ICCVAM Authorization Act states that ICCVAM
- > shall prepare ``reports to be made available to the public on its
- > progress under this Act," with the first report to be completed within
- > 12 months of enactment of the Act, and subsequent reports to be made
- > biennially thereafter. The fifth ICCVAM biennial progress report, which
- > summarizes ICCVAM activities and accomplishments for the years 2010 and
- > 2011, is now available.
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- > Summary of Report Highlights
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- > The Biennial Progress Report describes new initiatives and progress

- > by NICEATM and ICCVAM during the period from January 2010 through
- > December 2011. During the past two years, NICEATM, ICCVAM, and ICCVAM
- > member agencies contributed to the national and international
- > endorsement and adoption of 14 new and updated alternative safety
- > testing methods. Since ICCVAM was established, NICEATM, ICCVAM, and the
- > ICCVAM member agencies have contributed to the regulatory acceptance of
- > over 50 alternative methods that can be used to protect and improve the
- > health of people, animals, and the environment while reducing,
- > refining, and replacing animal use.
- > Selected highlights of NICEATM and ICCVAM activities described in
- > the Biennial Progress Report include:
- > On behalf of NICEATM and ICCVAM, NIEHS signed an amendment
- > to an international cooperation agreement to add the Republic of Korea
- > and its Korean Center for the Validation of Alternative Methods
- > (KoCVAM) to the International Cooperation on Alternative Test Methods
- > (ICATM). ICATM was established in 2009 by the United States, the
- > European Union, Japan, and Canada to expedite the worldwide validation
- > and regulatory acceptance of improved alternative test methods.
- > The Organisation for Economic Co-operation and Development
- > (OECD) adopted an international guidance document prepared by NICEATM
- > and ICCVAM that describes how to use two cytotoxicity assays to reduce
- > animal use for testing required to determine the poisoning potential of
- > chemicals. NICEATM led the international validation studies for the two
- > cytotoxicity assays, which can reduce animal use by up to 50% for each
- > test.
- > Federal agencies and the OECD adopted several new versions
- > and applications of the murine local lymph node assay (LLNA); an
- > alternative method recommended by ICCVAM to assess whether substances
- > may cause allergic contact dermatitis. The test methods reduce animal
- > use for each test by 20-40% and support expanded use of the LLNA for
- > nearly all testing situations. Two new ``green" versions of the LLNA
- > were adopted that do not require radioactive reagents and will allow
- > expanded use of the LLNA in laboratories worldwide.
- > Federal agencies adopted ICCVAM recommended alternative
- > test methods and procedures that will further reduce, refine, and
- > replace animal use for eye safety testing. These include the routine
- > use of medications to avoid most if not all pain and distress when it
- > is necessary to use animals for required safety testing, and the first
- > in vitro test method that can be used in a ``bottom-up" approach to
- > identify substances that are not considered eye hazards.
- > NICEATM, ICCVAM, and their ICATM partners convened the
- > first international workshop on alternative methods for human and
- > veterinary vaccine potency and safety testing. The workshop reviewed
- > the state of the science of alternative methods, and recommended
- > priority research needed to develop improved and more efficient test
- > methods that can also reduce, refine, and replace animal use. A focused
- > workshop on human and veterinary rabies vaccine test methods was held
- > in 2011 and additional focused workshops are planned for 2012 and 2013.
- > ICCVAM completed international evaluation of an in vitro
- > test method proposed as a screening test to identify substances with
- > potential endocrine activity. The test method uses engineered human
- > cells to identify substances that induce or inhibit activation of the
- > human estrogen receptor. Use of this test method may reduce the number
- > of animals necessary for endocrine disruptor screening.
- > NICEATM and ICCVAM convened two Best Practices for
- > Regulatory Safety Testing Workshops to promote the use of improved and
- > more efficient test methods that can also reduce, refine, and replace

- > animal use. Participants learned how to select and use approved
- > alternative methods to assess the safety or potential hazards of
- > chemicals and products.
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- > Background Information on ICCVAM and NICEATM
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- > ICCVAM is an interagency committee composed of representatives from
- > 15 Federal regulatory and research agencies that require, use,
- > generate, or disseminate toxicological and safety testing information.
- > ICCVAM conducts technical evaluations of new, revised, and alternative
- > safety testing methods with regulatory applicability and promotes the
- > scientific validation and regulatory acceptance of toxicological and
- > safety testing methods that more accurately assess the safety and
- > hazards of chemicals and products and that reduce, refine (enhance
- > animal well-being and lessen or eliminate pain and distress), or
- > replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C.
- > 285I-3) established ICCVAM as a permanent interagency committee of the
- > NIEHS under NICEATM. NICEATM administers ICCVAM, provides scientific
- > and operational support for ICCVAM-related activities, and conducts
- > independent validation studies to assess the usefulness and limitations
- > of new, revised, and alternative test methods and strategies. NICEATM
- > and ICCVAM welcome the public nomination and submission of new,
- > revised, and alternative test methods and strategies applicable to the
- > needs of U.S. Federal agencies. Additional information about NICEATM
- > and ICCVAM can be found on the NICEATM-ICCVAM Web site
- > (<http://iccvam.niehs.nih.gov>).
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- > Dated: June 4, 2012.
- > John R. Bucher,
- > Associate Director, National Toxicology Program.
- > [FR Doc. 2012-14436 Filed 6-12-12; 8:45 am]
- > BILLING CODE 4150-01-D