names, signatures, addresses, account numbers, or any other personally identifying information.

● Information (*e.g.* photographs) that demonstrates that the institution posts the disclosure required by 12 U.S.C. 1831t(b)(2) at each station or window where it normally receives deposits, the institution's principal place of business, and all the institution's branches where it accepts deposits or opens accounts (excluding automated teller machines and point of sale terminals).

● Copies of all non-identical advertising[10] issued or continued in use within the previous three months.

● Samples of the cards, forms, or other written materials the institution uses to comply with the signed acknowledgment requirements for new depositors pursuant to 12 U.S.C. 1831t(b)(3). The samples should not include any individual consumer names, signatures, addresses, account numbers, or any other personally identifying information.[11]

The Commission will use the collected information in its efforts to ensure that the institutions are complying with the disclosures required by the 12 U.S.C. 1831t(b).[12]

*B. Estimated Hours Burden*

Based upon its knowledge of the industry, the staff estimates, on average, that the time required to gather, organize, format, and produce such responses will average 8 hours per information request. Thus, allowing up to 200 recipients of the information requests, total burden would be approximately 1,600 hours.

*C. Estimated Cost Burden*

It is difficult to calculate with precision the labor costs associated with this data production, as they entail varying compensation levels of management and/or support staff among companies of different sizes. Managerial, legal, and clerical personnel may be involved in the information collection process. The FTC staff has assumed, conservatively, that managerial personnel and legal counsel will handle all of the tasks involved in gathering and producing responsive information, and has applied an average hourly wage of managerial time of $58.12/hour (4 hours per entity) and an average hourly wage of legal staff time of $40.87/hour (4 hours per entity).[13] Thus, cumulatively, estimated labor costs for the information requests will be $79,192 (($58.12 x 800 hours + $40.87 x 800 hours)). The actual cost may be lower to the extent clerical personnel handle some of the tasks.

FTC staff estimates that the capital or other non-labor costs associated with the information requests are minimal. We expect that industry members maintain most, if not all, of the requested material in the normal course of business because they must disclose the information to customers under existing law.

By direction of the Commission.

**Donald S. Clark**

*Secretary*

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[10] As used in these requests, the term ''advertising'' means any communication that the institution uses to solicit business including, but not limited to, printed materials, the institution's main internet page, radio advertisements, video advertisements disseminated via television, the Internet or any other means of online communication, and solicitations conducted via telephone.

[11] The requested documents should exclude any information for which prior customer authorization is required under the Right to Financial Privacy Act, 12 U.S.C. 3401, *et seq.*

[12] Although the Commission is currently in the process of developing regulations for these requirements, *see* 74 FR 18043 (Mar. 13, 2009), institutions lacking federal deposit insurance must comply with these statutory provisions regardless of the status of FTC's regulations in this area.

[13] Hourly wages are averages based on mean hourly wages shown in *http://www.bls.gov/oes/2008/may/naics4_551100.htm#b11-0000* (May 2008 ''National Industry-Specific Occupational Employment and Wage Estimates'') for sales and marketing managers and legal occupations (lawyers, paralegals, and other legal support), respectively.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of Alternative Ocular Safety Testing Methods and Approaches: Notice of Availability and Request for Public Comments

**AGENCY:** National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

**ACTION:** Request for comments.

**SUMMARY:** NICEATM, in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), convened an independent international scientific peer review panel (hereafter, Panel) on May 19–21, 2009, to evaluate test methods and approaches with the potential to reduce and refine the use of animals for ocular safety testing. These evaluations included the following:

- A proposal for the routine use of topical anesthetics, systemic analgesics, and humane endpoints to avoid and minimize pain and distress during in vivo ocular irritation testing.
- The in vivo low volume eye test (LVET).
- The use of the bovine corneal opacity and permeability (BCOP), the Cytosensor Microphysiometer® (CM), the isolated chicken eye (ICE), the isolated rabbit eye (IRE), and the hen's egg test—chorioallantoic membrane (HET–CAM) test methods for identifying moderate and mild ocular irritants and substances not labeled as ocular irritants.
- Nonanimal testing strategies that use the BCOP, CM, and/or EpiOcular™ (EO) test methods to assess the eye irritation potential of antimicrobial cleaning products to determine their appropriate U.S. Environmental Protection Agency ocular hazard classification.

The Panel report from this meeting is now available. The report contains (1) The Panel's evaluation of the validation status of the test methods and testing strategies and (2) the Panel's comments on the draft ICCVAM test method recommendations. NICEATM invites public comment on the Panel report. The report is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/docs/ocutox_docs/OcularPRPRept2009.pdf* or by contacting NICEATM at the address given below.

**DATES:** Written comments on the Panel report should be received by August 28, 2009.

**ADDRESSES:** NICEATM prefers that comments be submitted electronically by e-mail to *niceatm@niehs.nih.gov.* Comments can also be submitted via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm.* Written comments can be sent by mail or fax to Dr. William S. Stokes, Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709; (fax) 919–541–0947. Courier address: NIEHS, NICEATM, 530 Davis Drive, Room 2035, Durham, NC 27713.

**FOR FURTHER INFORMATION CONTACT:** Dr. William S. Stokes, (telephone) 919–541–2384, (fax) 919–541–0947 and (e-mail) *niceatm@niehs.nih.gov.*

**SUPPLEMENTARY INFORMATION:**

#### Background

NICEATM announced the convening of an independent scientific peer review

panel to review and comment on the draft background review documents (BRDs) and summary review documents (SRDs) and draft recommendations, as well as the availability of the draft documents for public comment, in March 2009 (74 FR 14556). The Panel met in public session on May 19–21, 2009, at Consumer Product Safety Commission Headquarters in Bethesda, MD. The Panel reviewed the draft ICCVAM documents for completeness, errors, and omissions of any existing relevant data or information. The Panel then evaluated the information in the draft documents to determine the extent to which each of the applicable criteria for validation and acceptance of toxicological test methods (ICCVAM 2003) had been appropriately addressed. The Panel then considered the ICCVAM draft recommendations and commented on the extent that the recommendations were supported by the information provided in the draft BRDs or SRDs.

ICCVAM organized a 2005 symposium (70 FR 18037) on Minimizing Pain and Distress in Ocular Toxicity Testing where experts recommended that topical anesthetics and systemic analgesics should be routinely administered before in vivo ocular safety testing to avoid or minimize pain and distress that might occur during and after the initial application of test substances. The experts also recommended that systemic analgesics should routinely be administered when there are clinical signs indicative of pain or distress. The experts further recommended that humane endpoints to end a study early should be identified and used routinely. ICCVAM requested data (72 FR 26396), compiled available information on the use of topical anesthetics, systemic analgesics, and humane endpoints during in vivo ocular safety testing, and developed draft recommendations for implementing such practices.

In 2007, ICCVAM published (70 FR 66451) recommendations on the use of four in vitro test methods (BCOP, ICE, IRE, HET–CAM) for identifying ocular corrosives and severe irritants for hazard classification and labeling purposes. The ICCVAM recommendations were submitted to and accepted by ICCVAM member agencies (more information at *http://iccvam.niehs.nih.gov/methods/ocutox/ivocutox/ocu_recommend.htm*). One of the ICCVAM recommendations was to consider the validation status of these four in vitro ocular test methods for identifying mild and moderate ocular irritants and substances not classified as ocular irritants. NICEATM and ICCVAM requested data (72 FR 31582), compiled available information, prepared draft BRDs assessing their current validation status for this purpose, and developed draft recommendations for their use.

In January 2008, a BRD titled, An In Vitro Approach for EPA Labeling of Anti-Microbial Cleaning Products, was submitted to NICEATM for review. This BRD, prepared by the Institute for In Vitro Sciences in collaboration with the Alternative Testing Working Group (comprised of seven consumer product companies [Clorox, Colgate Palmolive, Dial, EcoLabs, Johnson Diversey, Procter and Gamble, and SC Johnson]), proposes a testing strategy that uses the CM®, EpiOcular™, and BCOP test methods to assess the eye irritation potential of antimicrobial cleaning products and to determine appropriate EPA ocular hazard classification categories for such products. NICEATM and ICCVAM reviewed the BRD, requested additional data and information (73 FR 18535), and compiled draft recommendations and a draft ICCVAM SRD. ICCVAM also reviewed the validation status of the LVET, which is proposed as a reference test method to partially substantiate the validity of the in vitro test methods used in the test strategy.

**Availability of the Peer Panel Report**

The Panel's conclusions and recommendations are detailed in the Independent Scientific Peer Review Panel Report: Evaluation of the Validation Status of Alternative Ocular Safety Testing Methods and Approaches which is available along with the draft documents reviewed by the Panel and the draft ICCVAM test method recommendations at *http://iccvam.niehs.nih.gov/methods/ocutox/PeerPanel09.htm.*

**Request for Public Comments**

NICEATM invites the submission of written comments on the Panel report. When submitting written comments, please refer to this **Federal Register** notice and include appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, if applicable). All comments received will be made publicly available via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/ocutox/PeerPanel09.htm*. ICCVAM will consider the Panel report along with public comments and comments made by the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) at their June 25–26, 2009 meeting (74 FR 19562) when finalizing test method recommendations. Final ICCVAM recommendations will be published in ICCVAM test method evaluation reports, which will be forwarded to relevant Federal agencies for their consideration. The evaluation reports will also be available to the public on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/ocutox/ocutox.htm* and by request from NICEATM (see **ADDRESSES** above).

**Background Information on ICCVAM, NICEATM, and SACATM**

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use, generate, or disseminate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability, and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM administers ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of U.S. Federal agencies. Additional information about ICCVAM and NICEATM can be found on their Web site (*http://iccvam.niehs.nih.gov).*

SACATM was established January 9, 2002, and is composed of scientists from the public and private sectors (67 FR 11358). SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding the statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/* see ''Advisory Board & Committees'' (or directly at *http://ntp.niehs.nih.gov/go/167*).

**Reference**

ICCVAM. 2003. ICCVAM Guidelines for the Nomination and Submission of New, Revised, and Alternative Test Methods. NIH Publication No. 03–4508. Research Triangle Park, NC: NIEHS. Available at: *http://iccvam.niehs.nih.gov.*

Dated: July 3, 2009.

**John R. Bucher,**

*Associate Director, NTP.*

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