

misleading acts or practices alleged in the complaint.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Specifically, Part I of the proposed order addresses the allegedly unsubstantiated claims regarding the Oreck Halo. Part I covers any representation that the Oreck Halo or any other vacuum cleaner:

(1) Reduces the risk of or prevents the flu; (2) reduces the risk of or prevents illnesses or ailments caused by bacteria, viruses, molds, or allergens, such as the common cold, diarrhea, upset stomachs, asthma and allergy symptoms; (3) will eliminate all or virtually all germs, bacteria, dust mites, molds, viruses or allergens from a user's floor; and (4) will eliminate any percent or numerical quantity of germs, bacteria, dust mites, molds, viruses or allergens from a user's floor. Part I also applies to representations that ultraviolet light is effective against germs, bacteria, dust mites, molds, viruses or allergens embedded in carpets. Part I prohibits Oreck from making any of the above representations unless the representation is non-misleading and, at the time of making such representation, Oreck possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. The proposed order defines "competent and reliable scientific evidence" as "tests, analyses, research or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results."

Part II of the proposed order addresses the allegedly unsubstantiated claims regarding the Oreck ProShield Plus. Part II covers any representation that the Oreck ProShield Plus or any other air cleaner: (1) Reduces the risk of or prevents the flu; (2) reduces the risk of or prevents illnesses or ailments caused by bacteria, viruses, molds, or allergens, such as the common cold, asthma and allergy symptoms; (3) will eliminate all or virtually all indoor airborne particles under normal living conditions; and (4) will eliminate any percent or numerical quantity of indoor air contaminants under normal living conditions. Part II prohibits Oreck from making any of the above representations unless the representation is non-misleading and, at the time of making such representation, Oreck possesses

and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Part III of the proposed order prohibits respondent from making representations, other than representations covered under Parts I or II, about the absolute or comparative health benefits of any product, unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Part IV of the proposed order addresses the allegedly false claims that scientific tests prove that the Oreck Halo or ProShield Plus eliminate or virtually eliminate many common germs, viruses or allergens from the user's floor or air. Part IV prohibits respondent, when advertising any product, from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part VI of the proposed order requires the payment of \$750,000 intended for redress to consumers. To facilitate the payment of redress, Part V of the proposed order requires Oreck to provide to the Commission a searchable electronic file containing the name and contact information of all consumers who purchased the Oreck Halo or the Oreck ProShield Plus from January 1, 2009 through August 31, 2010.

Part VII of the proposed order requires Oreck to send a letter to all of its franchisees requesting that they immediately stop using all advertising and marketing materials previously provided to them by Oreck. The required letter is appended to the proposed order as Attachment A.

Parts VIII, IX, X and XI of the proposed order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to its personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part XII provides that the

order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify their terms in any way.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-0321]

### 30-Day Notice; Agency Information Collection Request; 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to

[Sherette.funncoleman@hhs.gov](mailto:Sherette.funncoleman@hhs.gov), or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-5806.

**Title:** HHS Web Site Customer Satisfaction Survey—0990-0321—Reinstatement with change—Office of the Assistant Secretary for Public Affairs.

*Abstract:* The results of the HHS Web Site Customer Satisfaction Survey will be used to ensure that the content on the

HHS Web sites meets visitor needs and expectations. The results will also

determine if the site is easy to use and the content easy to understand.

#### ESTIMATED ANNUALIZED BURDEN TABLE

Form	Number of respondents	Number of responses per respondent	Average burden hours per response (in hrs.)	Total burden hours
Survey .....	48,000	1	12/60	9,600

**Mary Forbes,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Recommendations on In Vitro Ocular Safety Testing Methods and Strategies and Routine Use of Topical Anesthetics, Systemic Analgesics, and Humane Endpoints for Ocular Safety Testing

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

**ACTION:** Notice of availability.

**SUMMARY:** U.S. Federal agency responses to ICCVAM test method recommendations on alternative testing methods and strategies proposed to further reduce and refine the use of animals for assessing the ocular hazard potential of chemicals and products are now available. ICCVAM recommended a pain management procedure that should always be used to avoid pain and distress when it is determined necessary to conduct the rabbit eye test for regulatory safety purposes. ICCVAM also recommended the Cytosensor Microphysiometer (CM) test method as a screening test (1) to identify some types of substances that will not cause sufficient injury to require eye hazard labeling and (2) to identify some types of substances that may cause permanent or severe eye injuries. ICCVAM previously forwarded recommendations to Federal agencies and made these recommendations available to the public (75 FR 57027). In accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3), agencies have notified ICCVAM in writing of their findings and ICCVAM is making these responses available to the public. Federal agency responses are available on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/>

[ocutox/Transmit-2010.htm](http://iccvam.niehs.nih.gov/methods/ocutox/Transmit-2010.htm). The ICCVAM recommendations are provided in ICCVAM test method evaluation reports that are available on the NICEATM-ICCVAM Web site at <http://iccvam.niehs.nih.gov/methods/ocutox/OcuAnest-TMER.htm>, <http://iccvam.niehs.nih.gov/methods/ocutox/MildMod-TMER.htm>, <http://iccvam.niehs.nih.gov/methods/ocutox/AMCP-TMER.htm>, and <http://iccvam.niehs.nih.gov/methods/ocutox/LVET.htm>.

**FOR FURTHER INFORMATION CONTACT:** 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, (e-mail) [niceatm@niehs.nih.gov](mailto:niceatm@niehs.nih.gov). Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

#### SUPPLEMENTARY INFORMATION:

##### Background

The U.S. Environmental Protection Agency (EPA) requested that ICCVAM (1) evaluate the current validation status of the bovine corneal opacity and permeability (BCOP), hen's egg test-chorioallantoic membrane (HET-CAM), isolated chicken eye (ICE), and isolated rabbit eye (IRE) test methods; (2) identify *in vivo* ocular toxicity reference data to support the validation of *in vitro* test methods; (3) explore ways of alleviating pain and distress from current *in vivo* ocular safety testing; and (4) review the state of the science and the availability of *in vitro* test methods for assessing mild or moderate ocular irritants. The highest priority activity, an evaluation of the BCOP, HET-CAM, ICE, and IRE test methods for their usefulness and limitations for identifying potential ocular corrosives and severe irritants, was completed in 2006 (NIH Publication No. 07-4517). Based on this evaluation, U.S. Federal agencies subsequently accepted the BCOP and ICE test methods for certain regulatory testing purposes without the need for animal testing. The Organisation for Economic Co-operation and Development (OECD) subsequently

adopted the BCOP and ICE test methods in 2009 as international OECD Test Guidelines 437 and 438, respectively (OECD 2009a, OECD 2009b). The International Organization for Standardization (ISO) adopted the BCOP and ICE test methods as ISO Standard 10993-10 in 2010 (ISO 2010).

ICCVAM recently completed additional test method evaluations relevant to the original EPA nomination and a subsequent EPA request that ICCVAM evaluate a proposed *in vitro* testing strategy for identifying the ocular hazard potential of antimicrobial cleaning products. Information is provided about ICCVAM's evaluation and the committee's recommendations for the alternative testing methods and strategies proposed to further reduce and refine the use of animals for assessing the ocular hazard potential of chemicals and products in four ICCVAM Test Method Evaluation Reports: (1) *Recommendations for Routine Use of Topical Anesthetics, Systemic Analgesics, and Humane Endpoints to Avoid or Minimize Pain and Distress in Ocular Safety Testing* (NIH Publication No. 10-7514), (2) *Current Validation Status of In Vitro Test Methods Proposed for Identifying Eye Injury Hazard Potential of Chemicals and Products* (NIH Publication No. 10-7553), (3) *Current Validation Status of a Proposed In Vitro Testing Strategy for U.S. Environmental Protection Agency Ocular Hazard Classification and Labeling of Antimicrobial Cleaning Products* (NIH Publication No. 10-7513), and (4) *Recommendation to Discontinue Use of the Low Volume Eye Test for Ocular Safety Testing* (NIH Publication No. 10-7515).

#### Agency Responses to ICCVAM Recommendations

In September 2010, ICCVAM forwarded final test method recommendations for ocular safety testing methods and strategies to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C.