DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Availability of Interagency Coordinating Committee on the Validation of Alternative Methods Test Method Evaluation Reports on Two Nonradioactive Versions of the Murine Local Lymph Node Assay for Assessing Allergic Contact Dermatitis Hazard Potential of Chemicals and Products, and Expanded Uses of the Local Lymph Node Assay for Pesticide Formulations and Other Products; Notice of Transmittal to Federal Agencies

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

ACTION: Availability of Reports; Notice of Transmittal.

SUMMARY: NICEATM announces availability of Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Test Method Evaluation Reports (TMERs) recommending two nonradioactive versions of the Local Lymph Node Assay (LLNA) for assessing allergic contact dermatitis (ACD) hazard potential of chemicals and products and expanded uses of the LLNA for pesticide formulations and other products. Related ICCVAM Test Method Recommendations in each report have also been transmitted to Federal agencies for their review and response to ICCVAM in accordance with the provisions of the ICCVAM Authorization Act of 2000. The LLNA: 5-Bromo-2′-deoxyuridine-Enzyme-Linked Immunosorbent Assay (BrdU-ELISA) and LLNA: Daicel Adenosine Triphosphate (DA) do not use radioactive reagents and therefore provide advantages in terms of reduced hazardous waste disposal and broader availability for use by laboratories that cannot use radioactive reagents. ICCVAM concludes that the accuracy and reliability of the LLNA: BrdU-ELISA and LLNA: DA support use of these test methods to identify substances as potential skin sensitizers or nonsensitizers. Based on an updated evaluation, ICCVAM is also recommending expanded use of the LLNA to evaluate the ACD hazard potential of pesticide formulations and other products.

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.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

ICCVAM previously evaluated the validation status of the LLNA as a stand-alone alternative method to the guinea pig maximization test (GPMT) and the Buehler test (BT) for assessing the ACD hazard potential of products and chemicals (NIH Publication No. 99–4494; available at *http://iccvam.niehs.nih.gov/methods/immunotox/llna.htm*). Based on this evaluation, ICCVAM recommended the LLNA as a valid substitute for the guinea pig test methods for most testing situations in 1999. The Environmental Protection Agency, the Food and Drug Administration, and the U.S. Consumer Product Safety Commission (CPSC) subsequently accepted the method as a valid substitute for the GPMT and BT. The Organization for Economic Co-operation and Development (OECD) subsequently adopted the LLNA as OECD Test Guideline 429 in 2002. Using the LLNA instead of guinea pig tests reduces and refines (less pain and distress) animal use for ACD safety testing.

In 2007, the CPSC nominated several new versions and applications of the LLNA to ICCVAM for evaluation of their scientific validity (*http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf*). The nomination requested that ICCVAM assess (1) the validation status of the LLNA limit dose procedure (*i.e.,* the reduced LLNA); (2) the modified LLNA test method protocols that do not require the use of radioactive materials; (3) the use of the LLNA to test mixtures, aqueous solutions, and metals; and (4) the use of the LLNA to determine ACD potency categories for hazard classification. NICEATM published a **Federal Register** notice (72 FR 27815) requesting public comments on (1) the appropriateness and relative priority of the CPSC-nominated LLNA activities, (2) the nomination of scientists to serve on an international independent scientific peer review panel, and (3) the submission of data from LLNA testing that related to the CPSC-nominated LLNA activities as well as corresponding data from human and other animal studies. ICCVAM assigned these activities a high priority after considering comments from the public and endorsement from the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). NICEATM and ICCVAM compiled comprehensive draft background review documents (BRDs), released them for public comment in January 2008 (73 FR 1360), and convened a public meeting of the panel on March 4–6, 2008 to peer review the draft documents. The panel evaluated the information in the BRDs as to whether it supported draft ICCVAM test method recommendations for test method uses and limitations, updated standardized test method protocols, and proposed future studies. The panel considered public comments made at the meeting, as well as public comments submitted in advance of the meeting, before concluding their deliberations. The panel's report was made available in May 2008 (73 FR 29136) for public comment. The draft ICCVAM BRDs, draft ICCVAM test method recommendations, the panel's report, and all public comments were made available to SACATM for comment at its meeting on June 18–19, 2008 (73 FR 25754).

After considering the conclusions and recommendations of the panel, comments from SACATM, and public comments, ICCVAM forwarded final recommendations for the updated LLNA test method protocol, the reduced LLNA, and LLNA performance standards to Federal agencies in September 2009 (74 FR 50212). ICCVAM concluded that the updated LLNA test method protocol will further reduce animal use by 20% compared to the original version of the LLNA and also provide for more consistent and reliable results. The reduced LLNA will reduce animal use by 40% for each test compared to the traditional, multi-dose LLNA. ICCVAM also recommended LLNA test method performance standards that can be used to efficiently evaluate the validity of modified versions of the LLNA that are mechanistically and functionally similar to the traditional LLNA. Federal agencies subsequently responded with their support and concurrence with the ICCVAM recommendations. Agency responses are available on the NICEATM–ICCVAM Web site.

NICEATM subsequently obtained additional data and/or information and revised the draft documents for both the traditional and nonradioactive LLNA methods. ICCVAM released the revised draft documents to the public for comment and announced a second meeting of the panel (74 FR 8974). The panel reconvened in public session on April 28–29, 2009 to review the ICCVAM-revised draft documents and

finalize its conclusions and recommendations on the current validation status of the nonradioactive test methods and the expanded uses of the LLNA for pesticide formulations and other products. The panel's report was made available for public comment in June 2009 (74 FR 26242). The revised draft ICCVAM BRDs, revised draft ICCVAM test method recommendations, the panel's report, and all public comments were made available to SACATM for comment on June 25–26, 2009 (74 FR 19562). After considering the conclusions and recommendations of the panel, comments from SACATM, and public comments, along with the recommendations of an OECD Expert Consultation on the LLNA convened in October and December 2009, ICCVAM finalized and forwarded test method recommendations to Federal agencies for their consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3(e)(4)). Agency responses to the ICCVAM test method recommendations will be made available on the NICEATM–ICCVAM website as they are received.

The ICCVAM TMERs, *The LLNA: BrdU–ELISA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication 10–7552), and *The LLNA: DA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication 10–7551), describe ICCVAM's recommendations for using the LLNA: BrdU–ELISA and LLNA: DA for regulatory hazard identification purposes. The reports also provide ICCVAM-recommended LLNA: BrdU–ELISA and LLNA: DA test method protocols, the final BRDs, and the peer review reports of the panel. The ICCVAM-recommended LLNA: BrdU–ELISA test method protocol is based on the protocol developed by Takeyoshi et al. (2001). The ICCVAM-recommended LLNA: DA test method protocol is based on the protocol developed by Idehara et al. (2008). Both test method protocols incorporate all relevant aspects of the recently updated ICCVAM-recommended traditional LLNA test method protocol (ICCVAM, 2009). The protocols also include reduced LLNA: BrdU–ELISA and LLNA: DA procedures that should always be considered and used where determined appropriate in order to further reduce animal use.

The ICCVAM Test Method Evaluation Report, *Using the Murine Local Lymph Node Assay for Testing Pesticide Formulations, Metals, Substances in Aqueous Solutions, and Other Products* (NIH Publication 10–7512) provides ICCVAM's updated evaluation and recommendations for use of the LLNA to evaluate the ACD hazard potential of pesticide formulations, metals, substances in aqueous solutions, and other products. The evaluation considered new data that became available subsequent to the original ICCVAM LLNA evaluation in 1999. The report also includes the peer review reports of the panel.

ICCVAM's evaluation of the LLNA for skin sensitization potency categorization is currently nearing completion, and final ICCVAM recommendations will be forwarded to Federal agencies later this year.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that require, 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 that refine, reduce, and replace animal use. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM (42 U.S.C 285l-3). 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. NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods for both validation studies as well as technical evaluations. Additional information about ICCVAM and NICEATM can be found on the NICEATM–ICCVAM 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/go/167.*

References

ICCVAM. 2010. ICCVAM Test Method Evaluation Report on The LLNA: BrdU–ELISA, A Nonradioactive Alternative Test Method to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products. NIH Publication Number 10–7552. Research Triangle Park, NC: National Institute of Environmental Health Sciences.

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assay based on 5-bromo-2'-deoxyuridine (BrdU) incorporation. Toxicology Letters 119(3): 203–208.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–09CJ]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC, or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Promoting HIV Testing among Low Income Heterosexual Young Adult Black Men—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The lifetime risk of acquiring HIV infection for black men is 1 in 16. Heterosexual transmission is the second highest category for HIV infection among black men, yet we know little about how to successfully access heterosexual black men with HIV prevention and testing messages. CDC is requesting OMB approval for 2 years to collect data for this 3-phase study. The data collection will take place in Queens and Brooklyn, New York.

The purpose of the proposed study is to elicit attitudes about HIV testing among a community-based sample of non-Hispanic black, heterosexual men, ages 18–25, who were recently arrested or who were recently released from jail/prison. The study will develop culturally-tailored and gender-specific educational materials that promote HIV testing among this population. The data collection process will take approximately 2 years.

There will be a screening for each phase, 30 respondents for the one-on-one, 300 respondents for the survey, and 40 for the focus group. In Phase 1, local investigators will conduct qualitative interviews with 20 non-Hispanic black, heterosexual men, ages 18–25, who were recently arrested or who were recently released from jail/prison and meet screening criteria. The interviews will identify their attitudes towards HIV testing, socio-cultural norms, and perceived behavioral control factors that influence HIV testing. The interviews will also elicit their opinions of how to promote HIV testing among their peers. Each interview will last approximately 1.5 hours. During Phase 2, the results from Phase I will be used to identify variables for a survey that will examine attitudes towards HIV testing, socio-cultural norms, and perceived behavioral control factors to HIV testing intentions and behaviors. The survey will include 250 non-Hispanic black heterosexual men, ages 18–25, who meet screening criteria. Each survey will last approximately 30 minutes.

During Phase 3, using Phase 1 and 2 results, educational materials promoting HIV testing among 24 non-Hispanic black heterosexual men will be developed and pilot tested in focus groups of young black men who meet screening criteria to evaluate the acceptability of the materials.

This study will provide important epidemiologic information useful for the development of HIV prevention interventions for young black men.

There is no cost to respondents except for their time. The estimated annualized burden hours are 265.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondents	Average burden per responses (hours)
General public	Screener for one-on-one interviews	30	1	10/60
General public	One-on-one interviews	20	1	1.5
General public	Screener for surveys	300	1	10/60
General public	Surveys	250	1	30/60
General public	Screener for focus groups	40	1	10/60
General public	Focus groups	24	1	2

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Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection