addressed to *OHQ@hhs.gov.* Written responses should be addressed to the Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite LL100, Rockville, MD 20852, Attention: Draft Phase 3 Long-Term Care Facilities Module.

FOR FURTHER INFORMATION CONTACT: Debra Nichols (240) 453–8264 or *OHQ@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

HAIs are among the leading causes of morbidity and mortality in the United States and the most common type of adverse event in the field of healthcare today. They are defined as localized or systemic adverse events, resulting from the presence of an infectious agent or toxin, occurring to a patient in a healthcare setting. An epidemiologic study by the Centers for Disease Control and Prevention (CDC) revealed that the subset of HAIs with hospital-onset accounted for approximately one in twenty hospital patients contracting an HAI. The fiscal cost is steep as well. HAIs contribute to an additional 28 to 33 billion dollars in healthcare expenditures annually.

For these reasons, the prevention and reduction of healthcare-associated infections is a top priority for the U.S. Department of Health and Human Services (HHS). Multiple agencies within HHS have been working to reduce the incidence and prevalence of HAIs for decades. To further efforts, the HHS Steering Committee for the Prevention of Healthcare-Associated Infections was established in July 2008 and charged with developing a comprehensive strategy to progress toward the elimination of HAIs.

In 2009, the Steering Committee issued the initial version of the National Action Plan to Prevent Healthcare-Associated Infections: Roadmap to Elimination. The initial strategy (Phase 1) focused on the prevention of infections in the acute care hospital setting and includes a prioritized research agenda; an integrated information systems strategy; policy options for linking payment incentives or disincentives to quality of care and enhancing regulatory oversight of hospitals; and a national messaging plan to raise awareness of HAIs among the general public, providers, and other stakeholder groups. The Action Plan also delineates specific measures and five-year goals to focus efforts and track national progress in reducing the most prevalent infections. In addition, the plan intended to enhance collaboration with non-government stakeholders and partners at the national, regional, state, and local levels to strengthen coordination and impact of efforts. Recognizing the need to coordinate prevention efforts across healthcare facilities, HHS released Phase 2 of the Action Plan in late 2010. Phase 2 expands efforts outside of the acute care setting into outpatient facilities (ambulatory surgical centers and end-stage renal disease facilities). Phase 2 of the Action Plan also addressed strategies to increase influenza vaccination coverage amongst healthcare personnel as influenza transmission to patients by healthcare personnel is well documented; healthcare personnel can acquire and transmit influenza from patients or transmit influenza to patients and other staff; and higher vaccination coverage among healthcare personnel has been associated with a lower incidence of healthcare-associated influenza cases.

The healthcare and public health communities are increasingly challenged to identify, respond to, and prevent HAIs across the continuum of settings where healthcare is delivered. The public health model's population-based perspective can be deployed to enhance HAI prevention, particularly given the shifts in healthcare delivery from the acute care (Phase 1) to ambulatory (Phase 2) and now to long-term care facilities with Phase 3.

The Steering Committee has drafted a strategy or modules that address HAI prevention in long-term care facilities, specifically nursing facilities and skilled nursing facilities. Similar to its Phase 1 & 2 efforts, Phase 3 Long-Term Care Facilities healthcare-associated infection reduction strategies expect to be executed through research and guideline development, implementation of national quality improvement initiatives at the provider level, and creation of payment policies that promote infection control and reduction in healthcare facilities.

To assist the Steering Committee in obtaining broad input in the development of the draft module, HHS, through this request for information (RFI), is seeking comments from stakeholders and the general public on the draft Phase 3 Long-Term Care Facilities module. The modules can be found at *http://www.hhs.gov/ash/initiatives/hai/actionplan/index.html#tier3.*

II. Information Request

The Office of Healthcare Quality, on behalf of the HHS Steering Committee for the Prevention of Healthcare-Associated Infections, requests input on the draft: ''Long-Term Care Facilities.'' In addition to general comments, the Steering Committee is seeking input on any additional gaps not addressed in the draft strategies.

III. Potential Responders

HHS invites input from a broad range of individuals and organizations that have interests in preventing and reducing healthcare-associated infections. Some examples of these organizations include, but are not limited to the following:

—General public
—Healthcare, professional, and educational organizations/societies
—Caregivers or health system providers (e.g., physicians, physician assistants, nurses, infection preventionists)
—State and local public health agencies
—Public health organizations
—Foundations
—Medicaid- and Medicare-related organizations
—Insurers and business groups
—Collaboratives and consortia

When responding, please self-identify with any of the above or other categories (include all that apply) and your name. Anonymous submissions will not be considered. The submission of written materials in response to the RFI should not exceed 10 pages, not including appendices and supplemental documents. Responders may submit other forms of electronic materials to demonstrate or exhibit concepts of their written responses. All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment.

Dated: July 17, 2012.

Don Wright,

Deputy Assistant Secretary for Health.

[FR Doc. 2012–17925 Filed 7–20–12; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Nomination of an In Vitro Test Method for the Identification of Contact Allergens: Request for Comments and Data

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

ACTION: Request for Comments and Data.

SUMMARY: On behalf of the Interagency Coordinating Committee on the Validation of Alternative Methods

(ICCVAM), the NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests public comment on an ICCVAM test method nomination for validation studies. The validation studies are proposed to determine the usefulness and limitations of an *in vitro* test method to identify electrophilic substances that have the potential to produce allergic contact dermatitis (ACD). NICEATM also requests data generated using *in vivo* and *in vitro* test methods for assessing ACD hazard potential, including but not limited to guinea pig methods, the murine local lymph node assay, the direct protein reactivity assay, the human cell line activation test, and the KeratinoSens™ assay. Data will be used to develop integrated testing and decision strategies that will also consider incorporation of the nominated test method following adequate validation studies.

DATES: Comments and test method data for assessing ACD hazard potential should be submitted by September 6, 2012. Comments and data submitted after this date will be considered in the evaluation where feasible.

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, (email) *niceatm@niehs.nih.gov*. Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The development of alternatives to animal testing for ACD is an ICCVAM priority (ICCVAM, 2008). See *http://iccvam.niehs.nih.gov/methods/immunotox/immunotox.htm* for more information on ICCVAM evaluations of ACD test methods.

Test Method Nomination for Validation Studies

An essential first step in the adverse outcome pathway for skin sensitization is the binding of a potential sensitizer to a dermal protein (Karlberg *et al.,* 2008). Chipinda and co-workers described a rapid screening assay for substances that might react with proteins using the substance nitrobenzenethiol, which contains a reactive thiol group found in proteins, as a probe (Chipinda *et al.,* 2010). Subsequently, a second probe, pyridoxalamine, was added to enable accurate detection of potential sensitizers that react with amine groups found in proteins. Covalent binding of the test substance to the probe is monitored by loss of absorbance or fluorescence. The modified assay identifies electrophilic skin sensitizers, but not prohaptens, which must be metabolized for skin sensitizing activity. The advantages of this assay include (1) The ability to obtain results using low test chemical concentrations, which reduces solubility problems; (2) the ability to run the assay without specialized equipment such as a high performance liquid chromatograph, a flow cytometer, or a mass spectrometer; the assays require only a simple spectrophotometer and fluorometer; (3) low cost; and (4) rapid results (assay time is less than half a day).

Once validation criteria have been appropriately addressed through validation studies, this method may have the potential to meet regulatory requirements for identifying skin sensitizers in a range of applications as a screening test and as a component of an integrated testing and decision strategy. The test developer from the National Institute of Occupational Safety and Health submitted a nomination requesting that NICEATM and ICCVAM evaluate this method as a screening assay for identification of contact allergens, and proposes collaborations with NICEATM to conduct validation studies and determine the most appropriate decision criteria to maximize the sensitivity and specificity of the *in chemico* assay. The cover letter for the nomination can be viewed on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov/SuppDocs/submission.htm#nomination).*

Draft ICCVAM Priority and Draft Recommended Activities

Based on the information provided by the test method developer and consideration of the ICCVAM prioritization criteria, ICCVAM considers that the nomination is of sufficient interest and applicability to warrant validation studies to characterize its usefulness and limitations for predicting ACD potential of chemicals and products. ICCVAM's draft position is that the nomination should have a high priority for the proposed studies. The ICCVAM preliminary evaluation of the method can be viewed on the NICEATM–ICCVAM Web site *(http://iccvam.niehs.nih.gov/methods/immunotox/EASA.htm).* ICCVAM proposed contributions to such studies would include review and comments on: (1) The optimization and standardization of the test method protocol, (2) the validation study design, and (3) reference chemical selection for the validation study. Federal agency programs will consider the nomination priority and recommended activities in determining potential support for validation activities.

As part of the nomination review process, NICEATM invites public comments on the relative draft priority assigned by ICCVAM and the appropriateness of the proposed activities. ICCVAM will finalize its recommendations on the priority and activities for this nomination after considering comments received from the public and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), which will comment on the ICCVAM draft recommendations at its meeting on September 5–6, 2012. Information about the SACATM meeting is available on the NTP Web site (*http://ntp.niehs.nih.gov/go/32822*).

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 and safety testing information. ICCVAM conducts technical evaluations of new, revised, and alternative safety testing methods and integrated testing strategies with regulatory applicability and promotes the scientific validation and regulatory acceptance of test methods that more accurately assess the safety and hazards of chemicals and products and that reduce, refine (enhance animal well-being and lessen or avoid pain and distress), or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–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 of new, revised, and alternative test methods and strategies for validation studies and 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 in response to the ICCVAM Authorization Act [Section 285*l*–3(d)] and is composed of scientists from the public and private sectors. SACATM advises ICCVAM, NICEATM, and the Director of the NIEHS and NTP regarding statutorily

mandated duties of ICCVAM and activities of NICEATM. SACATM provides advice on priorities and activities related to the development, validation, scientific review, regulatory acceptance, implementation, and national and international harmonization of new, revised, and alternative toxicological test methods. 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

Chipinda I, Ajibola RO, Morokinyo MK, Ruwona TB, Simoyi RH, Siegel PD. 2010. Rapid and simple kinetics screening assay for electrophilic dermal sensitizers using nitrobenzenethiol. Chem Res Toxicol 23: 918–925.

ICCVAM. 2008. The NICEATM–ICCVAM Five-Year Plan (2008–2012): A Plan to Advance Alternative Test Methods of High Scientific Quality to Protect and Advance the Health of People, Animals, and the Environment. NIH Publication No. 08–6410. Research Triangle Park, NC: NIEHS. Available: *http://iccvam.niehs.nih.gov/docs/5yearplan.htm.*

Karlberg A–T, Bergström MA, Börje A, Luthman, K, Nilsson JLG. 2008. Allergic Contact Dermatitis—Formation, Structural Requirements, and Reactivity of Skin Sensitizers. Chem Res Toxicol 21: 53–69.

Dated: July 11, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012–17788 Filed 7–20–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Evaluation of an Up-and-Down Procedure for Acute Dermal Systemic Toxicity Testing: Request for Nominations for an Independent Expert Panel and Submission of Relevant Data

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

ACTION: Request for Data; Request for Nominations of Scientific Experts.

SUMMARY: The NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), in collaboration with the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), is planning to convene an independent scientific peer review panel (Panel) to assess the validation status of an up-and-down procedure (UDP) for acute dermal systemic toxicity testing. NICEATM requests nominations of scientific experts who can be considered for the Panel and submission of data for substances tested in *in vivo* acute dermal and oral systemic toxicity tests.

DATES: Nominations and test method data for the acute dermal and oral tests should be submitted by September 6, 2012. Data submitted after this date will be considered in the evaluation where feasible.

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, (email) *niceatm@niehs.nih.gov.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

Acute poisoning from chemicals and chemical products, including pharmaceuticals, is a significant public health problem. In 2009, 2.5 million human poisoning cases were reported to U.S. poison control centers (Bronstein *et al.,* 2010). Dermal exposures were involved in 7.25% (179,832 cases) of the poisonings, which was second in frequency only to exposures by oral ingestion (2,080,781 cases). To protect workers and consumers from acute dermal poisoning exposures, regulatory agencies in the U.S. (e.g., the Environmental Protection Agency [EPA], the Consumer Products Safety Commission, Department of Transportation, Occupational Safety and Health Administration) use the information from acute dermal systemic toxicity tests using rabbits or rodents to determine the potential of chemicals and chemical products to cause life-threatening health effects or death from acute dermal exposures. Test results are used as the basis for hazard classification and labeling and to inform consumers and workers how to avoid acute dermal exposures to hazardous chemicals and products during the handling, transport, and use of chemicals and products.

In 2002, ICCVAM recommended the revised UDP for acute oral systemic toxicity as a replacement for the conventional test. The revised oral UDP was accepted internationally as Organisation for Economic Co-operation and Development (OECD) Test Guideline 425 in 2001 (OECD, 2001). The oral UDP reduces animal use by up to 70% compared to the traditional testing procedure. NICEATM is now developing a UDP procedure for acute dermal systemic toxicity testing, which is one of the four most commonly conducted product safety tests worldwide. Alternative test methods for acute dermal systemic toxicity testing are an ICCVAM priority because such testing is required by multiple agencies, can involve large numbers of animals, and can result in significant pain and distress to test animals (ICCVAM, 2008).

The acute dermal systemic toxicity UDP protocol is expected to reduce the number of animals used compared with current EPA (EPA, 1998) and OECD (OECD, 1987) test guidelines. A draft background review document (BRD) will include a proposed dermal UDP test method protocol and analyses comparing the results of simulated testing using the UDP protocol with the standard acute dermal systemic toxicity reference test described in EPA Health Effects Test Guidelines OPPTS 870.1200 (EPA, 1998) and OECD Test Guideline 402 (OECD, 1987). The draft BRD will form the basis for the ICCVAM draft test method recommendations for the proposed UDP method. Draft recommendations on usefulness and limitations, standardized test method protocol, and future studies will be provided to the Panel and made available to the public.

The Panel will meet in public session to review the validation status of the UDP for acute dermal systemic toxicity testing. The Panel will comment on the extent to which the BRD supports the draft ICCVAM test method recommendations. Meeting information, including dates, locations, and public availability of the meeting documents will be announced in a future **Federal Register** notice and will also be posted on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

Request for Nominations of Scientific Experts

NICEATM requests nominations of scientists with relevant knowledge and expertise to serve on the Panel. Areas of relevant expertise include, but are not limited to biostatistics; human and veterinary dermatology, with an emphasis on evaluation and treatment of chemical injuries that produce systemic effects; human and animal toxicology, especially systemic effects due to dermal exposures*; in vivo* dermal and oral toxicity testing; and test method validation. Each nomination should include the nominee's name, affiliation, contact information (i.e., mailing address, email address, telephone and fax numbers), *curriculum*