Background

ICCVAM originally recommended the LLNA as a valid stand-alone alternative method to existing ACD test methods in 1999 (NIH publication No. 99–4494; available at *http://iccvam.niehs.nih.gov/docs/immunotox_docs/llna/llnarep.pdf*). ICCVAM recommended that the LLNA could be used as a substitute for the existing guinea pig based test methods for most testing situations, which would reduce the number of animals required and avoid pain and distress. The Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC) subsequently accepted the method as a valid substitute. The Organization for Economic Co-operation and Development (OECD) adopted the LLNA as international OECD Test Guideline 429 and the International Standards Organization (ISO) adopted the LLNA as ISO Test 10993–10.

The updated LLNA test method protocol uses 20% fewer animals than the original LLNA protocol recommended by ICCVAM in 1999, and provides improved guidance on dose selection and other procedures to improve assay accuracy and reproducibility. The rLLNA procedure can further reduce the number of animals required by 40% compared to the updated LLNA protocol multi-dose procedure. ICCVAM recommends that the rLLNA test method should be routinely considered before conducting the traditional multi-dose LLNA, and should be used as the initial test for ACD where determined appropriate. ICCVAM evaluation and complete recommendations for the updated LLNA test method protocol and the rLLNA procedure are provided in the *ICCVAM Test Method Evaluation Report: The Reduced Murine Local Lymph Node Assay: An Alternative Test Method Using Fewer Animals to Assess the Allergic Contact Dermatitis Potential of Chemicals and Products* (NIH Publication No. 09–6439, available at *http://iccvam.niehs.nih.gov/methods/immunotox/LLNA–LD/TMER.htm*).

ICCVAM also recommends that the LLNA test method performance standards can be used to efficiently evaluate the validity of modified test methods that are mechanistically and functionally similar to the traditional LLNA. The LLNA test method performance standards are provided in the ICCVAM report, *Recommended Performance Standards: Murine Local Lymph Node Assay* (NIH Publication No. 09–7357, available at *http://iccvam.niehs.nih.gov/methods/immunotox/PerfStds/llna-ps.htm*).

ICCVAM evaluated the updated versions of the LLNA in response to a 2007 nomination from the CPSC (*http://iccvam.niehs.nih.gov/methods/immunotox/llnadocs/CPSC_LLNA_nom.pdf*). The nomination also requested that ICCVAM evaluate the validation status of (1) new versions of the LLNA test method protocol that do not require the use of radioactive materials; (2) use of the LLNA to test mixtures, aqueous solutions, metals, and other substances; and (3) use of the LLNA to determine ACD potency categories for hazard classification and labeling purposes. ICCVAM recommendations on these new versions and applications are undergoing finalization and will be forwarded to Federal agencies in 2010.

Agency Reponses to ICCVAM Recommendations

In September 2009, ICCVAM forwarded final test method recommendations for the rLLNA, the updated LLNA test method protocol, and LLNA performance standards to U.S. Federal agencies for consideration, in accordance with the ICCVAM Authorization Act of 2000 (42 U.S.C. 285l–3(e)(4)) (74 FR 50212). The ICCVAM Authorization Act requires member agencies to review ICCVAM test method recommendations and notify ICCVAM in writing of their findings no later than 180 days after receipt of recommendations. The Act also requires ICCVAM to make ICCVAM recommendations and agency responses available to the public. Agency responses are to include identification of relevant test methods for which the ICCVAM test method recommendations may be added or substituted, and indicate any revisions or planned revisions to existing guidelines, guidances, or regulations to be made in response to these recommendations.

Background Information on ICCVAM and NICEATM

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 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://www.iccvam.niehs.nih.gov).*

Dated: April 30, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2010–10954 Filed 5–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM): International Workshop on Alternative Methods To Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), Department of Health and Human Services.

ACTION: Announcement of a workshop.

SUMMARY: The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and NICEATM announce an upcoming "International Workshop on Alternative Methods to Reduce, Refine, and Replace the Use of Animals in Vaccine Potency and Safety Testing: State of the Science and Future Directions." The workshop will bring together an international group of scientific experts from government, industry, and academia to review the current state of the science, availability, and future need for alternative methods that can reduce, refine, and replace the use of animals for human and veterinary vaccine post-licensing potency and safety testing. Plenary and breakout sessions will address current U.S. and international regulatory requirements, currently available alternatives, and future research, development, and validation activities needed to further advance the use of alternative methods for vaccine post-licensing potency and safety testing. This workshop is free and open

to the public with attendance limited only by the space available. Abstracts for scientific posters for display at the workshop are also invited (*see* **SUPPLEMENTARY INFORMATION**).

DATES: The workshop will be held on September 14–16, 2010. Sessions will begin at 8:30 a.m. and end at approximately 5 p.m. on all days. The deadline for submission of poster abstracts is July 29, 2010. Individuals who plan to attend are asked to register in advance (by August 30, 2010) with NICEATM.

ADDRESSES: The workshop will be held at the William H. Natcher Conference Center, 45 Center Drive, NIH Campus, Bethesda, MD 20892. Persons needing special assistance, such as sign language interpretation or other reasonable accommodation in order to attend, should contact 919–541–2475 voice, 919–541–4644 TTY (text telephone), through the Federal TTY Relay System at 800–877–8339, or e-mail to *niehsoeeo@niehs.nih.gov.* Requests should be made at least 14 days in advance of the event.

FOR FURTHER INFORMATION CONTACT: Correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD K2–16, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

Vaccines represent a vital and cost-effective tool in the prevention of infectious diseases in humans and animals. Regulatory authorities require post-licensing potency and safety testing of human and veterinary vaccines to ensure their effectiveness and minimize potential adverse health effects. Because some of these tests require large numbers of laboratory animals that may experience unrelieved pain and distress, the development and validation of alternative methods that can reduce, refine, and replace the use of animals for vaccine potency and safety testing is one of ICCVAM's four highest priorities. The workshop goals are to (1) review the state of the science of alternative methods that are currently available and/or accepted for use that can reduce, refine (less pain and distress), and replace animal use in vaccine potency and safety testing, and discuss ways to promote their implementation; (2) identify knowledge and data gaps that should be addressed to develop alternative methods that can further reduce, refine, and/or replace the use of animals in vaccine potency and safety testing; and (3) identify and prioritize research, development, and validation efforts needed to address these knowledge and data gaps in order to advance alternative methods for vaccine potency and safety testing while ensuring the protection of human and animal health.

Preliminary Workshop Agenda

Day 1 Tuesday, September 14, 2010

- Welcome and Introduction of Workshop Goals and Objectives
- Overview of Public Health Needs and Regulatory Requirements for Vaccine Safety and Potency Testing
- Replacement Methods for Vaccine Potency Testing: Current State of the Science
- Breakout Groups: Non-animal Replacement Methods for Vaccine Potency Testing
- Human Vaccines
- Veterinary Vaccines

Day 2 Wednesday, September 15, 2010

- Refinement Alternatives: Using Serological Methods to Avoid Challenge Testing
- Refinement Alternatives: Using Earlier Humane Endpoints to Avoid or Minimize Animal Pain and Distress in Vaccine Potency Challenge Testing
- Reduction Alternatives: Strategies to Further Reduce Animal Numbers for Vaccine Potency Testing
- Breakout Groups: Refinement and Reduction of Animal Use for Vaccine Potency Testing
  - Human Vaccines
  - Veterinary Vaccines

Day 3 Thursday, September 16, 2010

- Vaccine Post-licensing Safety Testing: Reduction, Refinement and Replacement Methods and Strategies
- Breakout Groups: Post-license Vaccine Safety Testing: Alternative Strategies for the Replacement, Refinement, and Reduction of Animals
  - Human Vaccines
  - Veterinary Vaccines
- Closing Comments

Registration

Registration information, tentative agenda, and additional meeting information are available on the workshop Web site (*http://iccvam.niehs.nih.gov/meetings/BiologicsWksp-2010/BiologicsWksp.htm*) and upon request from NICEATM (*see* **FOR FURTHER INFORMATION CONTACT**).

Call for Abstracts

ICCVAM and NICEATM invite the submission of abstracts for scientific posters to be displayed during this workshop. Posters should address current research, development, validation, and/or regulatory acceptance of alternative methods that may reduce, refine, and/or replace the use of animals in vaccine potency or vaccine post-licensing safety testing. The body of the abstract must be limited to 400 words or fewer. Key references relevant to the abstract may be included after the abstract body. However, the length of the abstract and references should not exceed one page. All submissions should be at least 12-point font and all margins for the document should be no less than one inch. Title information should include names of all authors and associated institutions. The name and contact information (*i.e.,* address, phone number, fax number, e-mail address) for the corresponding or senior author should be provided at the end of the abstract.

A statement indicating whether animals or humans were used in studies described in the poster must accompany all abstracts. All abstracts that involve studies using animals or animal tissues should be accompanied by a statement by the senior author certifying that all animal use was carried out in accordance with applicable laws, regulations, and guidelines, and that the studies were approved by the appropriate Institutional Animal Care and Use Committee or equivalent. A statement that all human studies were conducted in accordance with applicable laws, regulations, and guidelines, and that the studies were approved by the appropriate Institutional Review Board or equivalent must accompany any abstracts that involve studies using humans.

Abstracts must be submitted by e-mail to *niceatm@niehs.nih.gov.* The deadline for abstract submission is close of business on July 29, 2010. ICCVAM and NICEATM will review the submitted abstracts. The corresponding author will be notified of the abstract's acceptance approximately five weeks prior to the workshop. Guidelines for poster presentations will be sent to corresponding authors along with the notification of acceptance.

Background Information on ICCVAM and NICEATM

ICCVAM is an interagency committee composed of representatives from 15 U.S. Federal regulatory and research agencies that require, use, or generate 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 health hazards of chemicals and products and that refine (less pain and distress), reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (42 U.S.C. 2851–2, 2851–5 [2000]), available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) 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 coordinates international validation studies. 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, guidelines for nomination of test methods for validation studies, and guidelines for submission of test methods for ICCVAM evaluation are available at *http://iccvam.niehs.nih.gov*.

Dated: April 30, 2010.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2010–10958 Filed 5–7–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0233]

The National Institutes of Health and the Food and Drug Administration Joint Leadership Council: Stakeholders Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting, in conjunction with the National Institutes of Health (NIH), to solicit comments from interested persons on how the agencies can more effectively collaborate to advance the translation of biomedical research discoveries into approved diagnostics and therapies as well as promote science to enhance the evaluation tools used for regulatory review. A newly formed NIH–FDA Joint Leadership Council will help ensure that regulatory considerations form an increasing component of biomedical research planning, and that the latest science is integrated into the regulatory review process.

DATES: The public meeting will be held on June 2, 2010, from 8:30 a.m. to 12:30 p.m. Persons interested in attending the meeting must register by Wednesday, May 26, 2010, at 5 p.m. e.s.t. (see section III of this document). Submit written or electronic comments by Wednesday, May 26, 2010, at 5 p.m. e.s.t.

ADDRESSES: The public meeting will be held at FDA, 10903 New Hampshire Ave., Bldg. 31, rm. 1503C, Silver Spring, MD 20993–0002.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets at the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rakesh Raghuwanshi, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4283, Silver Spring, MD 20993–0002, 301–796–4769, FAX: 301–847–8617, e-mail: *rakesh.raghuwanshi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

With the dramatic breakthroughs occurring in biomedical research discovery, new public health challenges on the rise, an ever-changing economic landscape resulting from globalization, and the prospect for fundamental changes to healthcare delivery in the United States, there is a pressing need for greater collaboration between FDA and NIH. Both NIH and FDA have the goals of translating science discoveries into medical products and therapies, and both NIH and FDA have important roles and contributions to make towards these efforts. To address these important areas of common interest, NIH and FDA announced a new partnership effort that includes, among other initiatives, the regulatory science program and the NIH–FDA Joint Leadership Council.

The NIH–FDA Joint Leadership Council provides a forum for the leadership of both agencies to: (1) Work together on strategic planning at a high level; (2) stimulate an enhanced culture of collaboration between the agencies at all levels; and (3) further coordinate and target efforts to promote promising new therapies using the latest technological advances, such as stem cell biology, biomarkers, and computational sciences. NIH and FDA plan to work jointly to address the gap between biomedical research discoveries and new medical products. They can create new programs to support development of innovative therapies and promote personalized medicine, utilizing new clinical trial design strategies and regulatory review processes incorporating the use of genetic or other biomarkers and information technologies. These activities will also support postmarketing and/or other population-based surveys for safety assessments. Overall, there are many new avenues for NIH and FDA to explore such that we can deliver safer and more effective treatments faster.

II. Scope of the Meeting

FDA and NIH are interested in receiving comments from the public on the regulatory considerations that should be an integral part of the biomedical research program development and scientific tools or approaches that would enhance the ability to evaluate new medical products. The comments should focus on ways in which NIH and FDA can partner to promote interdisciplinary biomedical research through scientific exchange and new programs designed to advance innovation and development of new therapies incorporating many of the latest basic research discoveries. Suggestions about the ways FDA and NIH can work together to promote an integrated biomedical research agenda including regulatory review approaches and/or processes on areas of common interest and mission are being sought. Some areas for which we are specifically interested in input are the following:

1. What steps should be taken to enhance the translation of biomedical research discoveries into new and approved preventatives, diagnostics, therapies, or devices for clinical use?

2. What are the priority scientific issues that currently need to be addressed (e.g., clinical trial design, endpoint selection and qualification, bioinformatics needs) in order to inform regulatory assessments and analyses of new products?

3. How could we enhance the exchange of scientific information across all sectors in order to better identify and prioritize scientific areas for emphasis in regulatory research?

4. What mechanisms for the support of regulatory science research would be most effective and efficient in addressing pressing priority areas in the translational pipeline?

III. Registration To Attend and/or To Participate in the Meeting

If you wish to attend the public meeting, you must register by e-mailing Rakesh Raghuwanshi