FEDERAL MEDICAL ASSISTANCE PERCENTAGES AND ENHANCED FEDERAL MEDICAL ASSISTANCE PERCENTAGES, EFFECTIVE OCTOBER 1, 2010–SEPTEMBER 30, 2011—Continued

[Fiscal year 2011]

State	Federal medical assistance percentages	Enhanced federal medical assistance percentages
New Mexico	69.78	78.85
New York	50.00	65.00
North Carolina	64.71	75.30
North Dakota	60.35	72.25
Northern Mariana Islands *	50.00	65.00
Ohio	63.69	74.58
Oklahoma	64.94	75.46
Oregon	62.85	74.00
Pennsylvania	55.64	68.95
Puerto Rico *	50.00	65.00
Rhode Island	52.97	67.08
South Carolina	70.04	79.03
South Dakota	61.25	72.88
Tennessee	65.85	76.10
Texas	60.56	72.39
Utah	71.13	79.79
Vermont	58.71	71.10
Virgin Islands *	50.00	65.00
Virginia	50.00	65.00
Washington	50.00	65.00
West Virginia	73.24	81.27
Wisconsin	60.16	72.11
Wyoming	50.00	65.00

* For purposes of section 1118 of the Social Security Act, the percentage used under titles I, X, XIV, and XVI will be 75.00 per centum.

** The values for the District of Columbia in the table were set for the State plan under titles XIX and XXI and for capitation payments and DSH allotments under those titles. For other purposes, the percentage for DC is 50.00 per centum, unless otherwise specified by law.

[FR Doc. E9–28438 Filed 11–25–09; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Toxicology Program (NTP); NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Evaluation of In Vitro Estrogen Receptor Transcriptional Activation and In Vitro Cell Proliferation Assays for Endocrine Disruptor Chemical Screening: Request for Nominations for an Independent Expert Peer Review Panel and Submission of Relevant In Vitro and In Vivo Data

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

ACTION: Request nominations for an independent expert panel and submission of relevant data.

SUMMARY: 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 (hereafter, Panel) to assess the validation status of an *in vitro* stably-transfected estrogen receptor (ER) transcriptional activation (TA) Assay (LUMI–CELL® ER assay) and an *in vitro* cell proliferation assay (CertiChem MCF–7 Cell Proliferation assay) for their usefulness and limitations in determining whether and to what extent chemicals can interact with estrogen receptors *in vitro.*

Validated assays that can detect the interaction of chemicals with specific hormone receptors including the ER are included in the U.S. Environmental Protection Agency (EPA) Endocrine Disruptor Screening Program (EDSP) (*http://www.epa.gov/endo/pubs/assayvalidation/status.htm*). The two assays that will undergo peer review are currently undergoing validation studies to determine their usefulness and limitations for the EDSP. Any other existing data from these two assays are requested to ensure that all available relevant data are considered by the Panel. Data from other existing *in vitro* and *in vivo* assays for the 78 reference substances used for the validation studies (available at *http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf*) are requested for use in characterizing the expected *in vitro* and *in vivo* activity of these 78 reference substances. At this time NICEATM requests:

- Nominations of expert scientists for consideration as potential Panel members.
- Submission of existing data from the LUMI–CELL® ER and the CertiChem MCF–7 Cell Proliferation assays.
- Submission of data from *in vivo* or other *in vitro* assessments for the 78 reference substances recommended by ICCVAM for the validation of *in vitro* ER and AR binding and TA test methods (available at *http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf*).

DATES: Submit nominations and data by January 11, 2010. Data submitted after this date will be considered in the evaluation, where feasible.

ADDRESSES: Submit nominations and data electronically by e-mail to *niceatm@niehs.nih.gov,* or via the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/contact/FR_pubcomment.htm.* Nominations and data may also 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, (telephone) 919–541–2384, (fax) 919–541–0947, (e-mail). Courier address: NIEHS, NICEATM, 530 Davis Drive, Room 2034, Morrisville, NC 27560.

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

In April 2000, the EPA requested that ICCVAM evaluate the validation status of *in vitro* ER and AR binding and TA assays for potential use in the proposed EPA EDSP. ICCVAM and NICEATM compiled available relevant data for 137 existing assays and compiled data were submitted to an independent expert panel for review. This panel concluded that there were no adequately validated *in vitro* ER- or AR-based test methods (the panel's report is available on the NICEATM–ICCVAM Web site at *http://iccvam.niehs.nih.gov/methods/endocrine/end_EPrpt.htm*). Based on these conclusions and recommendations, along with comments from the public, ICCVAM recommended minimum procedural standards and a list of 78 reference substances that should be used to standardize and validate *in vitro* ER and AR binding and TA test method protocols. These recommendations were made publicly available in the report: *ICCVAM Evaluation of the In Vitro Methods for Detecting Potential Endocrine Disruptors: Estrogen Receptor and Androgen Receptor Binding and Transcriptional Activation Assays* (available at: *http://iccvam.niehs.nih.gov/methods/endocrine/end_TMER.htm*). The list of 78 reference substances was subsequently modified because of cost and availability considerations and published in a separate Addendum (available at: *http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf*).

Two *in vitro* assays to detect ER agonists and antagonists were subsequently nominated to ICCVAM for validation studies in response to an ICCVAM request (69 FR 21564): The LUMI–CELL® ER assay developed by Xenobiotic Detection Systems, Inc. (XDS) and the CertiChem MCF–7 Cell Proliferation assay developed by CertiChem, Inc. (CertiChem). Based on preliminary results provided for these test methods and comments from the public and the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM; 69 FR 21564 and 71 FR 60748, respectively), ICCVAM and its Endocrine Disruptor Working Group recommended a high priority for validation studies for the LUMI–CELL® ER and CertiChem MCF–7 Cell Proliferation assays.

An international interlaboratory validation study of the LUMI–CELL® ER assay is currently nearing completion. The study includes three laboratories sponsored by NICEATM, the European Centre for the Validation of Alternative Methods, and the Japanese Center for the Validation of Alternative Methods. An intralaboratory validation study of the MCF–7 Cell Proliferation assay has been completed by CertiChem in conjunction with NICEATM, and an interlaboratory study is planned.

NICEATM will prepare draft background review documents (BRDs) following completion of the validation studies that will provide comprehensive summaries of available data, analyses of test method accuracy and reliability, and related information characterizing the current validation status of each of the assays. The draft BRDs will form the basis for draft ICCVAM test method recommendations on usefulness and limitations, standardized test method protocols, future studies, and performance standards that will subsequently 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 LUMI–CELL® ER, MCF–7 Cell Proliferation assays, and any of the other assays for which there are adequate data available. The Panel will comment on the extent to which the BRD supports draft ICCVAM test method recommendations. The Panel may also consider the results for other assays with incomplete validation databases to determine their current validation status and to identify data gaps that need to be addressed in order to further characterize their usefulness and limitations for the EDSP. Meeting information, including dates, locations, and public availability of the BRDs will be announced in future **Federal Register** notices and will also be posted on the ICCVAM/NICEATM Web site (*http://iccvam.niehs.nih.gov/methods/endocrine/end_eval.htm*).

Request for Nominations of Scientific Experts

NICEATM requests nominations of scientists with relevant knowledge and experience to serve on the Panel. Areas of relevant expertise include, but are not limited to, biostatistics, cellular biology, endocrinology, molecular genetics, regulatory toxicology, reproductive toxicology, 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 vitae,* and a brief summary of relevant experience and qualifications.

Request for Data

NICEATM invites the submission of relevant *in vitro* and *in vivo* data and information for reference substances on the list of 78 substances recommended by ICCVAM for standardizing and validating *in vitro* ER and AR binding and TA test methods (available at *http://iccvam.niehs.nih.gov/docs/endo_docs/EDAddendFinal.pdf*) or other substances for which data exists from the two *in vitro* test methods described in this notice. Relevant *in vivo* data may include, but are not limited to: Multi-generational reproductive and developmental toxicity studies, uterotrophic bioassays, and short term assays assessing changes in phenotypic parameters such as anogenital distance, time of vaginal opening, nipple retention, and preputial separation delays in males.

Although data can be accepted at any time, data received by January 11, 2010 will ensure consideration during the ICCVAM evaluation process. Relevant data received after this date will be considered during the ICCVAM evaluation process where feasible. All information submitted in response to this notice will be made publicly available and may be incorporated into future NICEATM and ICCVAM reports and publications as appropriate.

When submitting data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable).

NICEATM prefers that data be submitted as copies of pages from study notebooks and/or study reports, if available. Laboratory data and analyses available in electronic format may also be submitted. Each submission for a substance should preferably include the following information, as appropriate:

- Common and trade name
- Chemical Abstracts Service Registry Number (CASRN)
- Commercial source
- *In vivo* or *in vitro* test protocol used
- Individual animal or *in vitro* responses at each observation time (*i.e.,* laboratory data)
- The extent to which the data were collected in accordance with national/international Good Laboratory Practice guidelines
- Date and testing organization
- Physical and chemical properties (*e.g.,* molecular weight, pH, water solubility, *etc.*)

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that 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 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, available at *http://iccvam.niehs.nih.gov/docs/about_docs/PL106545.pdf*) 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 Federal agencies. Additional information about ICCVAM and NICEATM is available 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*.

Dated: November 16, 2009.

John R. Bucher,

Associate Director, National Toxicology Program.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Screening Framework Guidance for Synthetic Double-Stranded DNA Providers

AGENCY: Department of Health and Human Services, Office of the Secretary.

ACTION: Notice.

Authority: Public Health Service Act, 42 U.S.C. 241, Section 301; HSPD–10.

SUMMARY: To reduce the risk that individuals with ill intent may exploit the commercial application of nucleic acid synthesis technology to access genetic material derived from or encoding Select Agents or Toxins, the U.S. Government has developed recommendations for a framework for synthetic nucleic acid screening. This document is intended to provide guidance to producers of synthetic genomic products regarding the screening of orders so that these orders are filled in compliance with current U.S. regulations and to encourage best practices in addressing potential biosecurity concerns. Following this guidance is voluntary, though many specific recommendations serve to remind providers of their obligations under existing regulations. The target audience for this guidance is the gene and genome synthesis industry, because the technical hurdles for *de novo* synthesis of Select Agents and Toxins from double-stranded DNA are much lower than for *de novo* synthesis of these agents from single-stranded oligonucleotides. This guidance proposes a screening framework for commercial providers of synthetic double-stranded DNA 200 base pairs (bps) or greater in length to address concerns associated with the potential for misuse of their products. The framework includes customer screening and sequence screening, follow-up screening as necessary, and consultation with U.S. Government contacts, as needed.

This guidance is submitted for public consideration and comment for a period of 60 days. The Office of the Assistant Secretary of Preparedness and Response (ASPR) within the Department of Health and Human Services (HHS) is submitting this document for public consideration as the lead agency in a broad interagency process to draft the guidance.

DATES: The public is encouraged to submit written comments on this proposed action. Comments may be submitted to HHS/ASPR in electronic or paper form at the HHS/ASPR e-mail address, mailing address, and fax number shown below under the heading **FOR FURTHER INFORMATION CONTACT.** All comments should be submitted by January 26, 2010. All written comments received in response to this notice will be available for review by request.

FOR FURTHER INFORMATION CONTACT: Jessica Tucker, Ph.D., Office of Medicine, Science, and Public Health, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services, 330 C Street, SW., Room 5008B, Washington, DC 20201; phone: 202–260–0632; fax: 202–205–8494; e-mail address: *asprfrcorrespondence@hhs.gov*.

SUPPLEMENTARY INFORMATION:

Screening Framework Guidance for Synthetic Double-Stranded DNA Providers

I. Summary

Synthetic biology, the developing interdisciplinary field that focuses on both the design and fabrication of novel biological components and systems as well as the re-design and fabrication of existing biological systems, is poised to become the next significant transforming technology for the life sciences and beyond. Synthetic biology is not constrained by the requirement of using existing genetic material. Thus, technologies that permit the directed synthesis of polynucleotides have great potential to be used to generate organisms, both currently existing and novel, including pathogens that could threaten public health, agriculture, plants, animals, the environment, or material. To reduce the risk that individuals with ill intent may exploit the commercial application of nucleic acid synthesis technology to access genetic material derived from or encoding Select Agents or Toxins, the U.S. Government has developed recommendations for a framework for synthetic nucleic acid screening. This document is intended to provide guidance to producers of synthetic genomic products regarding the screening of orders so that these orders are filled in compliance with current U.S. regulations and to encourage best practices in addressing potential biosecurity concerns.

Following this guidance is voluntary, though many specific recommendations serve to remind providers of their obligations under existing regulations. The target audience for this guidance is the gene and genome synthesis industry, because the technical hurdles for *de novo* synthesis of Select Agents and Toxins from double-stranded DNA are much lower than for *de novo* synthesis of these agents from single-stranded oligonucleotides. This guidance proposes a screening framework for commercial providers of synthetic double-stranded DNA 200 base pairs (bps) or greater in length to address concerns associated with the potential for misuse of their products. The framework includes customer screening and sequence screening, follow-up screening as necessary, and consultation with U.S. Government contacts, as