MD 20993–0002, 301–796–5661 at least 7 days before the public workshop.

SUPPLEMENTARY INFORMATION:

I. Why are we holding this public workshop?

The purpose of the public workshop is to facilitate discussion between FDA and other interested parties on the use of computational modeling in medical device design, development and evaluation.

II. What are the topics we intend to address at the public workshop?

We hope to discuss a large number of issues at the public workshop, with our overall theme being the validation of computer models with nonclinical models. Topics include, but are not limited to the following:

- Advancing Computational Modeling Studies—how is computational modeling being used for device design, development, and/or evaluation?
- Best Validation Practices—what validation scheme has worked for computational model systems?
- Lessons Learned—what validation schemes have been unsuccessful for computational model systems?
- Data Resources—where are data for boundary conditions, loading conditions, material properties, etc. obtained for model systems?

III. Where can I find out more about this public workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, food services, and other relevant information will be posted, as it becomes available, on the Internet at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm* (or go to *http://www.fda.gov* and select the FDA Medical Devices News & Events—Workshops & Conferences calendar and select this public workshop from the posted events list).

Dated *August 8, 2011.*

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20446 Filed 8–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

The Development and Evaluation of Next-Generation Smallpox Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) and the National Institutes of Health, the National Institute of Allergy and Infectious Diseases are announcing a public workshop entitled ''The Development and Evaluation of Next-Generation Smallpox Vaccines.'' The purpose of the public workshop is to identify and discuss the key issues related to the development and evaluation of next-generation smallpox vaccines. The public workshop will include presentations on the human response to smallpox vaccines and development of animal models for demonstration of effectiveness of next-generation smallpox vaccines.

Date and Time: The public workshop will be held on September 16, 2011, from 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Hilton Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Bernadette Williamson-Taylor, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, *Fax:* 301–827–3079, *e-mail: CBERTraining@fda.hhs.gov* (in the subject line type ''Smallpox Workshop'').

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone, and fax numbers) to the contact person by August 23, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact Bernadette Williamson-Taylor (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: Smallpox is a serious, highly contagious, and sometimes fatal infectious disease. Although the World Health Organization declared the disease eradicated in 1980, the threat of smallpox as a biological weapon remains. Vaccination is the only prevention for the disease and there are currently no FDA-approved treatments.

First-generation smallpox vaccines were prepared on the skin of calves or other animals or in chicken eggs. Although these vaccines were not evaluated for efficacy in well-controlled trials, they were highly effective as evidenced by the successful global eradication of smallpox. Manufacturing of these vaccines has ceased and they are no longer licensed in the United States.

In 2007, FDA licensed the first second-generation smallpox vaccine, ACAM2000. This vaccine is based on a single plaque-purified vaccinia virus derivative of Dryvax (a previously licensed first-generation vaccine) and is aseptically propagated using cell culture technology under modern manufacturing practices and standards. Both ACAM2000 and Dryvax are derived from the New York City Board of Health strain and produce a vesicular or pustular lesion (referred to as a ''vaccine take'') that has been shown to correlate with protection. In clinical trials, ACAM2000 elicited vaccinia-neutralizing antibodies and cell-mediated immune responses, with both clinical and immunological outcomes similar to Dryvax.

Because ACAM2000 may cause serious adverse reactions, there is a desire to develop safer vaccines should there be a need to vaccinate the general population due to a threat of an attack with the smallpox virus. Currently, the next-generation smallpox vaccines under development do not produce the characteristic ''vaccine take.'' In addition, it is not ethical or feasible to evaluate the effectiveness of these vaccines in humans as the natural disease has been eradicated. Therefore, the effectiveness of these next-generation smallpox vaccines may be based on animal efficacy data, if scientifically appropriate, and to comparative human immune response data. As for any biologic product, licensure of new smallpox vaccines requires demonstration of safety, purity, and potency.

The public workshop will: (1) Discuss regulatory challenges and approaches related to the licensure of next-generation smallpox vaccines; (2) discuss the strengths and weaknesses of various animal models relative to their ability to mimic human disease that can be used to predict the effectiveness of

next-generation smallpox vaccines in humans; (3) discuss the most appropriate methods to bridge immunogenicity of next-generation smallpox vaccines to licensed smallpox vaccines in clinical trials; and (4) discuss viable methods of extrapolating clinical efficacy of next-generation smallpox vaccines from immunogenicity and efficacy data from relevant animal models.

Transcripts: Transcripts of the public workshop may be requested in writing from the Division of Freedom of Information Office (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page. A transcript of the public workshop will be available on the Internet at *http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm.*

Dated: August 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20367 Filed 8–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; *telephone:* 301–496–7057; *fax:* 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Tumor Markers for Potentially Predicting Outcome of Anti-angiogenesis Therapy

Description of Technology: During the past decade, anti-angiogenesis therapy has evolved as a promising approach to the treatment of cancer. However, a significant fraction of patients do not benefit from anti-angiogenesis therapy, either by itself or in combination with chemotherapy. A significant need remains for a means of predicting clinical benefit from anti-angiogenesis therapy.

Researchers at the National Cancer Institute, NIH, have identified tumor cell apoptosis, p53, and HER2 as having potential predictive significance for treatment outcome in breast cancer patients who received anti-angiogenesis therapy in combination with chemotherapy. The researchers have developed a quantitative antibody-based testing method for correlating expression of p53 and HER2 and tumor apoptosis with clinical outcome. These markers can be potentially applied to predict which patients should receive anti-angiogenesis therapy plus chemotherapy.

Potential Commercial Applications:

• A diagnostic kit for predicting benefit of anti-angiogenesis therapy plus chemotherapy in breast cancer patients.

• A testing service for breast cancer patients.

Competitive Advantages:

• The clinical predictive markers p53, HER2 and tumor apoptosis indicators are easily and readily evaluated using the new assay.

• The new assay is potentially useful to determine which patients should or should not receive anti-angiogenesis therapy plus chemotherapy for longer survival and progression-free survival in patients with breast cancer.

• A study with a large sample size will be planned by the inventors and potential collaborators.

Development Stage:

• Pilot.

• In vivo data available (human).

Inventors: Sherry Yang (NCI), Seth Steinberg (NCI), *et al.*

Publication: Yang S, *et al.* p53, HER2 and tumor cell apoptosis correlate with clinical outcome after neoadjuvant bevacizumab plus chemotherapy in breast cancer. Int J Oncol. 2011 May; 38(5):1445–1452. [PMID 21399868]

Intellectual Property: HHS Reference No. E–096–2011/0—U.S. Patent Application No. 61/448,092 filed 01 March 2011

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; mccuepat@mail.nih.gov

Collaborative Research Opportunity: The National Clinical Target Validation Laboratory, DCTD, NCI, NIH, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize p53, tumor apoptosis, and HER2 as markers for anti-angiogenesis therapy. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov.*

TRRAP and GRIN2A Mutations for the Diagnosis and Treatment of Melanoma

Description of Technology: Using whole-exome sequencing of matched normal and metastatic tumor DNAs, researchers at the NIH have identified several novel somatic (*e.g.,* tumor-specific) alterations, many of which have not previously been known to be genetically altered in tumors or linked to melanoma. In particular, the researchers identified a recurrent ''hotspot'' mutation in the transformation/transcription domain-associated protein (TRRAP) gene, found the glutamate receptor ionotropic N-methyl D-aspartate 2A (GRIN2A) gene as a highly mutated in melanoma, and have shown that the majority of melanoma tumors have alterations in genes encoding members of the glutamate signaling pathway. Therefore, this technology not only provides a comprehensive map of genetic alterations in melanoma, but has important diagnostic and therapeutic applications. Mutations in the TRRAP and GRIN2A genes can be used as diagnostic markers for melanoma and may serve as therapeutic targets in the treatment of melanoma. In addition, glutamate antagonists have previously been shown to inhibit proliferation of human tumor cells, and therefore further investigation of the pathway in melanoma could allow for the identification of new therapeutic proteins that target this pathway.

Potential Commercial Applications:

• Diagnostic array for the detection of TRRAP and GRIN2A mutations.

• Method of identifying TRRAP and GRIN2A inhibitors as therapeutic agents to treat malignant melanoma patients.

• Method of selecting a therapy based on the presence of TRRAP and GRIN2A mutations.

Competitive Advantages:

• Complete analysis of melanoma exome alterations.

• TRRAP, GRIN2A, and the other identified mutations are highly frequent and/or highly mutated in melanomas.

• Glutamate antagonists have already been shown to inhibit tumor growth. Thus, this technology may prove useful