

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 24, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 16, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 17, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Cindy Hong at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 8, 2016.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2016-02857 Filed 2-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0268]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On December 9, 2015, the Agency submitted a proposed collection of information entitled "Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration" to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0728. The approval expires on January 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-02880 Filed 2-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0148]

#### Government-Owned Inventions; Availability for Licensing; Influenza Virus Neuramindase

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed in this document is owned by an Agency of the U.S. Government and is available for licensing in accordance with Federal regulations to achieve expeditious commercialization of results of Federally funded research and development.

#### FOR FURTHER INFORMATION CONTACT:

*For licensing information and copies of the patent applications:* Alice Welch, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4226, Silver Spring, MD 20993, 240-402-2561, FAX: 301-847-3539. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

*For parties interested in licensing or collaborative research activities:* William Ronnenberg, Technology Transfer Program Office, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4214, Silver Spring, MD 20993, 240-402-4561, [William.ronnenberg@fda.hhs.gov](mailto:William.ronnenberg@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

Technology description.

*Title of Abstract:* Therapeutic and prophylactic anti-Influenza virus neuraminidase 1 (N1) antibody (CD6) with a novel epitope that spans neuramindase (NA) dimers.

*Description of Technology:* Influenza virus neuramindase (NA) protein is a surface protein that plays an essential role in virus replication. Drugs and antibodies that block NA function can reduce both the symptoms and the length of illness; however, variants of influenza virus are resistant to NA inhibitors. The neuramindase 1 (N1) subtype of NA is important because it is found in the two pandemic H1N1 influenza virus strains (1918 Spanish flu and 2009 swine flu) and the H5N1 avian influenza virus. Anti-neuramindase antibody CD6 is a novel antibody that spans a conserved 30 amino acid epitope across the lateral face of a neuramindase (NA) dimer.

The subject technology may offer an alternative to therapeutic NA inhibitors

currently available. CD6 is a potent monoclonal antibody against N1 subtypes of NA that inhibits the enzymatic activity of the NA protein, including NA variants resistant to NA inhibitors. In a murine model of infection, a single dose of antibody was protective against lethal challenge with H1N1 influenza virus. The CD6 antibody can potentially be used in combination with other antibodies in an antibody “cocktail” or in conjunction with other therapeutic agents. Additionally, this unique anti-NA antibody may be useful in combination with known neutralizing anti-hemagglutinin (HA) antibodies.

#### Potential Commercial Applications

- Prophylactic and therapeutic against influenza virus infections;
- Diagnostic tests for influenza virus infections; and
- Reagent to measure the potency of H1N1 NA in influenza virus vaccines.

#### Competitive Advantages

- Monoclonal antibody demonstrated to be effective against circulating H1N1 influenza viruses;
- Monoclonal antibody binds a novel, conserved epitope spanning NA dimers; and
- Monoclonal antibody is well-suited for an antibody cocktail that includes anti-HA antibodies.

*Development Stage:* Early stage; In vitro data available; In vivo data available (animal).

*Inventors:* Hongquan Wan (FDA); Maryna Eichelberger (FDA); Hua Yang (CDC); James Stevens (CDC); David Shore (CDC); and Rebecca Garten (CDC).

*Publication:* Wan, H., H. Yang, D. A. Shore, R. J. Garten, L. Couzens, J. Gao, L. Jiang, P. J. Carney, J. Villanueva, J. Stevens, and M. C. Eichelberger. “Structural Characterization of a Protective Epitope Spanning A(H1N1)pdm09 Influenza Virus Neuraminidase Monomers.” 6:6114, *Nature Communications*, 2015.

*Intellectual Property:* HHS Reference No. E-005-2015/0—U.S. Provisional Patent Application No. 62/088,388 filed December 5, 2014.

*Licensing and Collaborative Research Opportunity:* The invention is owned by an Agency of the U.S. Government and is available for licensing in accordance with 35 U.S.C. 209 and 37 CFR part 404.

The Food and Drug Administration is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Parties interested in licensing or collaborative research activities for this technology should

contact William Ronnenberg (see **FOR FURTHER INFORMATION CONTACT**).

Dated: February 4, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-02887 Filed 2-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0742]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** On July 8, 2015, the Agency submitted a proposed collection of information entitled “Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0045. The approval expires on December 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: February 8, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-02881 Filed 2-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Annual Computational Science Symposium; Conference

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public conference.

**SUMMARY:** The Food and Drug Administration, in cosponsorship with the Pharmaceutical Users Software Exchange (PhUSE) is announcing a public conference entitled “The FDA/PhUSE Annual Computational Science Symposium.” The purpose of the conference is to help the broader community align and share experiences to advance computational science. At the conference, which will bring together FDA, industry, and academia, FDA will update participants on current initiatives, and collaborative project groups will address specific challenges in accessing and reviewing data to support product development. These project groups will focus on solutions and practical ways to implement them.

**DATES:** The meeting will be held on March 13, 2016, from 3 p.m. to 7 p.m., and March 14 to 15, 2016, from 9 a.m. to 5:30 p.m.

**ADDRESSES:** The meeting will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1-240-777-5300.

**FOR FURTHER INFORMATION CONTACT:** Chris Decker, PhUSE FDA Liaison Director, Pharmaceutical Users Software Exchange (PhUSE), Kent Innovation Centre, Broadstairs, Kent CT10 2QQ, United Kingdom; 1-609-514-5105 (US), [css@phuse.eu](mailto:css@phuse.eu).

**SUPPLEMENTARY INFORMATION:**

#### I. Background

Since 2008, the Office of Computational Science (formerly the Computational Science Center) of FDA’s Center for Drug Evaluation and Research (CDER) has supported CDER’s scientific community by offering innovative solutions that improve the scientific drug review process by integrating data, tools, services, and training. Since the first Computational Science Symposium four years ago, FDA has played an important part in the development and ongoing support of the conference and the associated PhUSE Computational Science Working Groups. The PhUSE Collaboration was formed to bring together experts from industry, FDA and other regulatory agencies, academia, and