

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 state; 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.

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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.

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