

withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 3, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is available for licensing 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.

**FOR FURTHER INFORMATION CONTACT:**

Amy F. Petrik, Ph.D., 240-627-3721, [amy.petrik@nih.gov](mailto:amy.petrik@nih.gov). Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

#### Stabilized Group 2 Influenza Hemagglutinin Stem Region Trimers and Uses Thereof

*Description of Technology:*

Researchers at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases (NIAID) have designed influenza vaccine candidates based on group 2 influenza hemagglutinin (HA) proteins. These group 2 HA proteins were engineered to remove the highly variable head region and stabilize the remaining stem region. The researchers then fused the engineered group 2 HA stabilized stem with a ferritin subunit. The resulting fusion protein can self-assemble into nanoparticles which display group 2 HA stem domain trimers on their surface.

These immunogens elicit cross-reactive antibodies to group 2 influenza viruses and could be used in combination with group 1 HA stem-ferritin immunogens as a universal influenza vaccine. Interestingly, a recent study by Andrews et al., *Sci. Immunol.* 2, eaan2676 (2017), suggests that cross-reactive group 1/group 2 HA stem antibodies may be more likely to be elicited in humans by a group 2 HA immunogen.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

*Potential Commercial Applications:*

- Use as a broadly protective influenza vaccine

*Competitive Advantages:*

- Elicits antibodies to both group 1 and group 2 influenza A viruses
- Nucleic acid or recombinant protein-based vaccine
- Increased ease of production compared to current seasonal influenza vaccines

*Development Stage:*

- In vivo (animal studies)

*Inventors:* Jeffrey C. Boyington, Barney S. Graham, John R. Mascola, Hadi M. Yassine, Syed M. Moin, Lingshu Wang, Kizzmekia S. Corbett, Masaru Kanekiyo (all from NIAID).

*Intellectual Property:* HHS Reference Number E-228-2016 includes U.S. Provisional 62/383,267 filed 2 September 2016 and PCT Patent Application No. PCT/US2017/049894 filed 1 September 2017 (pending).

*Related Intellectual Property:* HHS Reference Number E-293-2011.

*Licensing Contact:* Dr. Amy Petrik, 240-627-3721; [amy.petrik@nih.gov](mailto:amy.petrik@nih.gov).

Dated: July 25, 2018.

**Suzanne M. Frisbie,**

*Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

[1651-0138]

#### Agency Information Collection Activities: Biometric Identity

**AGENCY:** U.S. Customs and Border Protection (CBP), Department of Homeland Security.

**ACTION:** 30-Day notice and request for comments; revision and extension of an existing collection of information.

**SUMMARY:** The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

**DATES:** Comments are encouraged and will be accepted (no later than September 10, 2018) to be assured of consideration.

**ADDRESSES:** Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to [dhsdeskofficer@omb.eop.gov](mailto:dhsdeskofficer@omb.eop.gov).

**FOR FURTHER INFORMATION CONTACT:**

Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229-1177, Telephone number (202) 325-0056 or via email [CBP\\_PRA@cbp.dhs.gov](mailto:CBP_PRA@cbp.dhs.gov). Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877-227-5511, (TTY) 1-800-877-8339,