

withdrawn from sale for reasons of safety or effectiveness.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.

[FR Doc. 2018-17026 Filed 8-8-18; 8:45 am]

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. 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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 Kanehiko (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.

Dated: July 25, 2018.

Suzanne M. Frisbie,

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

[FR Doc. 2018-17036 Filed 8-8-18; 8:45 am]

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.

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. 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,

or CBP website at <https://www.cbp.gov/>.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (83 FR 24326) on May 25, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Biometric Identity.

OMB Number: 1651-0138.

Type of Review: Revision and Extension (with change).

Current Actions: This submission is being made to revise the information collection and extend the expiration date with a change to the burden hours due to an increase in the number of respondents in agency estimates and separating the different biometric modalities. *Proposed Change:* CBP is proposing to revise this collection of information to include the collection of biometrics from certain travelers entering and exiting the United States in vehicles. This collection will not impose a time burden on the respondents and may reduce wait times at the ports of entry and exit.

Affected Public: Individuals.

Abstract: In order to enhance national security, the Department of Homeland Security is developing a biometric based entry and exit system capable of improving the information resources available to immigration and border management decision-makers. These biometrics may include: Digital fingerprint scans, facial images, iris images or other biometrics. Biometrics may be collected from certain travelers entering or exiting the United States in order to verify identity, determine admissibility of those seeking entry into the United States, confirm exit from the United States for the purpose of tracking aliens who have overstayed their visa or are otherwise illegally present in the United States, prevent visa fraud, and identify known or suspected criminals or terrorists. CBP will only store biometric data from those aliens specified in 8 CFR 215.8 and 8 CFR 235.1. U.S. Citizens and aliens who are generally exempt from biometric collection but voluntarily participate in biometric collection will have their biometrics deleted from DHS systems. CBP continues to test and evaluate different technological and operational changes to improve the accuracy and speed of biometric collection.

The federal statutes that mandate DHS to create a biometric entry and exit system include: Section 2(a) of the Immigration and Naturalization Service Data Management Improvement Act of 2000 (DMIA), Public Law 106-215, 114 Stat. 337 (2000); Section 205 of the Visa Waiver Permanent Program Act of 2000, Public Law 106-396, 114 Stat. 1637, 1641 (2000); Section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107-56, 115 Stat. 272, 353 (2001); Section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107-173, 116 Stat. 543, 552, (2002); Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108-458, 118 Stat. 3638, 3817 (2004); Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110-53, 121 Stat. 266 (2007), Consolidated Appropriations Act, 2016, Public Law 114-113, 129 Stat. 2242, 2493 (2016), Section 110 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104-208, 110 Stat. 3009-546 (1997), Section 802 of the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114-125, 130 Stat. 122, 199 (2015), and Sections 214, 215(a), 235(a),

262(a), 263(a) and 264(c) of the Immigration and Nationality Act of 1952, as amended, 8 U.S.C. 1184, 1185(a), 1225(a), 1302(a)(1303(a), 1304(c) and 1365b.

Fingerprint Modality

Estimated Number of Respondents: 58,657,882.

Estimated Time per Response: .0097 hours.

Estimated Total Annual Burden Hours: 568,981.

Facial/Iris Modality

Estimated Number of Respondents: 54,542,118.

Estimated Time per Response: .0025 hours.

Estimated Total Annual Burden Hours: 136,355.

Biometrics Collected From Travelers in Vehicles

Estimated Number of Respondents: 300,000.*

Estimated Time per Response: None.

Estimated Total Annual Burden Hours: None.

* Vehicle time per Respondent is estimated at zero due to no physical response required from the respondent.

Dated: August 6, 2018.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2018-17079 Filed 8-8-18; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2018-0002; Internal Agency Docket No. FEMA-B-1843]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment