on the label (2,160 − 1,140 = 1,020 products not organics; 540 − 285 = 255 manufacturers of not organic products). In addition, the 54 livestock feed suppliers are also organic producers, thus the 216 products attributed to these manufacturers already are considered to be labeled ''organic.'' Thus, there are 1,020 products made by 255 human food and pet food manufacturers that would need to substantiate that their product or ingredient was not genetically engineered.

We estimate that the burden of maintaining the documentation is a one-time burden; the document to substantiate that the product or ingredient was produced without genetic engineering only needs to be generated once and then kept on file. To annualize this one-time burden, we divide by 3 because paperwork burden collections are approved on a 3-year cycle (255/3 = 85). Thus, we estimate in table 1 that, on average, 85 manufacturers annually will collect and keep information that substantiates their label claim for four products (1,020 products/3 = 340 products/85 manufacturers = 4 products per manufacturer).

We estimate this one-time recordkeeping burden to be 1 hour per product that makes use of a labeling claim, which results in a burden of 1 hour for a total annualized recordkeeping burden of 340 hours (85 manufacturers × 4 records per manufacturer × 1 hour per record).

We do not estimate any reporting burden or third-party disclosure burden associated with this information collection. Manufacturers who want to make use of this voluntary labeling claim option are considered to be those that already have such wording on their products' labels. We do not expect that this guidance will cause labels already in the marketplace to need to be reworded.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–17024 Filed 8–8–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–0998]

Determination That PROLIXIN (Fluphenazine Hydrochloride) Tablets, 1 Milligram, 2.5 Milligrams, 5 Milligrams, and 10 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that PROLIXIN (fluphenazine hydrochloride) tablets, 1 milligram (mg), 2.5 mg, 5 mg, and 10 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for fluphenazine hydrochloride tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, is the subject of NDA 011751, held by Apothecon Pharmaceuticals, a Bristol-Myers Squibb Company, and initially approved on March 15, 1967. PROLIXIN is indicated in the management of manifestations of psychotic disorders.

In a letter dated October 5, 2006, Bristol-Myers Squibb Company requested withdrawal of NDA 011751 for PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg. In the **Federal Register** of February 11, 2009 (74 FR 6896), FDA announced that it was withdrawing approval of NDA 011751, effective March 13, 2009.

Hyman, Phelps & McNamara, P.C. submitted a citizen petition dated March 5, 2018 (Docket No. FDA–2018–P–0998), under 21 CFR 10.30, requesting that the Agency determine whether PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of PROLIXIN (fluphenazine hydrochloride) tablets, 1 mg, 2.5 mg, 5 mg, and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was

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 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.*

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,