the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on March 22, 2022.

As a result of this pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act (21 U.S.C. 335a(b)(3)(D)), FDA sent Mr. Lesniak, by certified mail on October 17, 2022, a notice proposing to debar him for a 5-year period from importing or offering for import any drug into the United States. In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Mr. Lesniak's pattern of conduct and concluded that his conduct warranted the imposition of a five-year period of debarment. The proposal informed Mr. Lesniak of the proposed debarment and offered him an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Lesniak received the proposal and notice of opportunity for a hearing on October 22, 2022. Mr. Lesniak failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment. (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Wojciech Lesniak has engaged in a pattern of importing or offering for import misbranded drugs (*i.e.* in an amount, frequency, or dosage that is inconsistent with his personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Lesniak is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Lesniak is a prohibited act.

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03958 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–P–1013]

Determination That CHANTIX (Varenicline Tartrate) Tablets, 0.5 Milligram and 1 Milligram, Has Not Been 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 CHANTIX (varenicline tartrate) tablets, 0.5 milligram (mg) and 1 mg, has not been withdrawn from sale for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: David Faranda, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6258, Silver Spring, MD 20993–0002, 301–796–8767, *David.Faranda@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 has been 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 approval of 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.

CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, is the subject of NDA 021928, held by PF Prism CV (c/o Pfizer Inc.), and initially approved on May 10, 2006. CHANTIX is indicated for use as an aid to smoking cessation treatment.

PF Prism CV has voluntarily discontinued marketing of CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg. The levels of the N-nitroso-varenicline (NNV) impurity in Chantix exceeded FDA's acceptable intake limit.[1] FDA's current understanding is

[1] Nitrosamine impurities in the drug supply are an important public health concern to which the Agency is dedicating significant resources. As explained in FDA's Guidance for Industry, *Control of Nitrosamine Impurities in Human Drugs,* ''Nitrosamine compounds are potent genotoxic agents in several animal species and some are classified as probable or possible human carcinogens by the International Agency for Research on Cancer (IARC). They are referred to as ''cohort of concern'' compounds in the ICH guidance for industry *M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk* (March 2018).'' Many drug products have been found to contain levels of nitrosamines that are unacceptable or require further evaluation. FDA's current understanding is that nitrosamine levels in affected drug products have different causes and may be controlled using different strategies, including formulation design (*i.e.,* adding antioxidants or adding pH adjusters that modify the microenvironment to base or neutral pH) and supplier qualification programs.

that the NNV impurity can be controlled within the acceptable intake limit by sponsors of varenicline products within the context of their particular applications.

CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Medley Pharmaceuticals Ltd. submitted a citizen petition dated June 6, 2022 (Docket No. FDA–2022–P–1013), under 21 CFR 10.30, requesting that the Agency determine whether CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, were 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 CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, has not been withdrawn for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities.

Accordingly, the Agency will continue to list CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 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. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs, including satisfying any applicable acceptable intake limit for nitrosamine impurities. 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: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03947 Filed 2–24–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: CDR George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, by mail at 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of Health and Human Services (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. The Secretary delegated this responsibility to the HRSA Administrator. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation (KFF) Employer Health Benefits Survey.

In 2022, Medical Expenditure Panel Survey-Insurance Component, available at *www.meps.ahrq.gov,* published the annual 2021 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was $7,380. This figure is divided by 12 to determine the cost per month of $615.00. The $615.00 figure is increased or decreased by the percentage change reported by the most recent KFF Employer Health Benefits Survey, available at *www.kff.org.* The increase from 2021 to 2022 was 2.2 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is $628.53.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is $628.53 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on February 21, 2023.

Carole Johnson,

Administrator.

[FR Doc. 2023–03919 Filed 2–24–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915–0311—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than April 28, 2023.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer, at 301–594–4394.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.