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CFR 10.30, requesting that the Agency determine whether CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, were withdrawn from sale for reasons of safety or effectiveness.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time, FDA has determined under § 314.161 that CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, has not been withdrawn for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable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.