copyright, or licensing agreement. The purpose of the financial information is for FDA to determine if there is a conflict of interest between the Fellow's or Trainee's financial and relationship interests and their activities at FDA. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Oak Ridge Institute for Science and Education Fellowship	500	500	500	1	500
Traineeship Program	500	500	500	1	500
Reagan Udall Fellowship at FDA	50	50	50	1	50
Total					1050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14439 Filed 7–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1358]

Jhanna Novikov: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jhanna Novikov for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Novikov was convicted of one felony count under Federal law for smuggling goods into the United States. The factual basis supporting Ms. Novikov's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Novikov was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of April 8, 2022 (30 days after receipt of the notice), Ms. Novikov had not responded. Ms. Novikov's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable July 7, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On December 9, 2021, Ms. Novikov was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Southern District of Florida-West Palm Beach Division, when the court accepted her guilty plea and entered judgment against her for the offense of smuggling goods into the United States, in violation of 18 U.S.C. 545. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the indictment, filed on July 28, 2021, and the plea agreement, filed on September 30, 2021, both from Ms. Novikov's case, on July 25, 2018, Ms. Novikov agreed to treat the facial wrinkles of an individual who was an undercover investigator with the Florida Department of Health with ''fillers'' for $600 and ''BOTOX'' for $300. BOTOX, or botulinum neurotoxin Type A, is the most well-known neurotoxin approved by FDA to treat facial wrinkles. On August 10, 2018, the investigator returned to Ms. Novikov's residence for her ''BOTOX'' treatment, and as Ms. Novikov made preparations and drew a liquid into a syringe, agents from FDA's Office of Criminal Investigations (OCI) entered and took control of her residence. After obtaining a warrant, OCI agents searched Ms. Novikov's home. Agents seized various vials of white powder from Ms. Novikov's residence, including two labeled ''NEUROXIN Botulinum Toxin Type A,'' 14 labeled ''CASPIS,'' and one with no label. Analysis by the FDA Forensic Chemistry Center determined that the two Neuroxin vials, a sample of four of the Caspis vials, and the unlabeled vial all contained botulinum toxin, the active ingredient in BOTOX; however, a search of FDA records revealed that these drugs had not been approved by FDA and were unapproved new drugs as well as misbranded drugs. Agents did not find any BOTOX or other FDA-approved drugs containing botulinum toxin in Ms. Novikov's home. A subsequent forensic examination of Ms. Novikov's cell phone, which had been seized by OCI agents, revealed that she had imported these unapproved new drugs from Mexico, in violation of the FD&C Act, and Ms. Novikov had been importing such drugs since 2016.

As a result of this conviction, FDA sent Ms. Novikov, by certified mail, on March 1, 2022, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Novikov's felony conviction under Federal law for smuggling goods into the United States, in violation of 18

U.S.C. 545, was for conduct relating to the importation into the United States of any drug or controlled substance because she illegally imported unapproved new drugs containing botulinum toxin to use in treatments she conducted on individuals for money. 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 Ms. Novikov's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Novikov of the proposed debarment, offered her an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Novikov received the proposal and notice of opportunity for a hearing at her residence on March 9, 2022. Ms. Novikov failed to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Jhanna Novikov has been convicted of a felony under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offense 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, Ms. Novikov 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 or controlled substance by, with the assistance of, or at the direction of Ms. Novikov is a prohibited act.

Any application by Ms. Novikov for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–1358 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14433 Filed 7–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Lists of Designated Primary Medical Care, Mental Health, and Dental Health Professional Shortage Areas

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

ACTION: Notice.

SUMMARY: This notice informs the public of the availability of the complete lists of all geographic areas, population groups, and facilities designated as primary medical care, dental health, and mental health professional shortage areas (HPSAs) in a designated status as of April 29, 2022. The lists are available on the shortage area topic page on HRSA's *data.hrsa.gov* website. Given the COVID–19 pandemic's impact on the health workforce and health care service delivery, HRSA is providing a longer transition time for jurisdictions and facilities to prepare for potential change of HPSA designations. HPSA designations that are currently proposed for withdrawal will remain in this status until they are re-evaluated in preparation for the publication of the 2023 HPSA **Federal Register** Notice. If these HPSAs do not meet the requirements for designation at the time of the publication of the July 2023 HPSA **Federal Register** Notice next year, they will be withdrawn. This additional time will allow jurisdictions to re-evaluate their HPSAs against the designation criteria, and plan for potential changes in staffing.

ADDRESSES: Complete lists of HPSAs designated as of April 29, 2022, and updated information on HPSAs are available on the website at *https://data.hrsa.gov/topics/health-workforce/shortage-areas.* Information on shortage designations is available at *https://bhw.hrsa.gov/workforce-shortage-areas/shortage-designation.*

FOR FURTHER INFORMATION CONTACT: For further information on the HPSA designations listed on the website or to request additional designation, withdrawal, or reapplication for designation, please contact Janelle D. McCutchen, DHEd, MPH, CHES, Chief, Shortage Designation Branch, Division of Policy and Shortage Designation, Bureau of Health Workforce (BHW), HRSA, 5600 Fishers Lane, Room 11W14, Rockville, Maryland 20857, *sdb@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 332 of the Public Health Service (PHS) Act, 42 U.S.C. 254e, provides that the Secretary shall designate HPSAs based on criteria established by regulation. HPSAs are defined in section 332 to include (1) urban and rural geographic areas with shortages of health professionals, (2) population groups with such shortages, and (3) facilities with such shortages. Section 332 further requires that the Secretary annually publish lists of the designated geographic areas, population groups, and facilities. The lists of HPSAs are to be reviewed at least annually and revised as necessary.

Final regulations (42 CFR part 5) were published in 1980 that include the criteria for designating HPSAs. Criteria were defined for seven health professional types: primary medical care, dental, psychiatric, vision care, podiatric, pharmacy, and veterinary care. The criteria for correctional facility HPSAs were revised and published on March 2, 1989 (54 FR 8735). The criteria for psychiatric HPSAs were expanded to mental health HPSAs on January 22, 1992 (57 FR 2473). Currently funded PHS Act programs use only the primary medical care, mental health, or dental HPSA designations.

HPSA designation offers access to potential federal assistance. Public or private nonprofit entities are eligible to apply for assignment of National Health Service Corps personnel to provide primary medical care, mental health, or dental health services in or to these HPSAs. National Health Service Corps health professionals enter into service agreements to serve in federally designated HPSAs. Entities with clinical training sites located in HPSAs are eligible to receive priority for certain residency training program grants administered by HRSA's Bureau of Health Workforce (BHW). Other federal programs also utilize HPSA designations. For example, under authorities administered by the Centers for Medicare and Medicaid Services, certain qualified providers in geographic area HPSAs are eligible for