I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act. On June 27, 2017, Mr. Cadden was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against him in the U.S. District Court for the District of Massachusetts, after a jury verdict, for one count of racketeering in violation of 18 U.S.C. 1962(c), one count of racketeering conspiracy in violation of 18 U.S.C. 1962(d), 52 counts of mail fraud in violation of 18 U.S.C. 1341, and three counts of introduction of misbranded drugs into interstate commerce with the intent to defraud and mislead-no prescriptions in violation of 21 U.S.C. 353(b)(1), 331(a), and 333(a)(2).

As contained in counts 1–2, 4–39, 41–56, 95, and 99–100 of the indictment, filed on December 16, 2014, Mr. Cadden was an owner and director of the New England Compounding Center (NECC), which held itself out as a compounding-only pharmacy, and he served as NECC's president, head pharmacist, and Manager of Record. In addition, Mr. Cadden was an owner and director of Medical Sales Management, Inc. (MSM), and served as MSM's Treasurer. MSM provided sales and administrative services to NECC for which MSM was paid a service fee. MSM's sales representatives sold drugs on behalf of NECC to customers throughout the country. In those capacities, Mr. Cadden instructed the MSM sales force to falsely represent to customers that NECC was providing the highest quality compounded medications, when in fact Mr. Cadden, among other things, failed to properly sterilize drug products consistent with applicable U.S. Pharmacopeia standards, failed to test purportedly sterile drugs, authorized the shipping of drugs before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients. Additionally, Mr. Cadden directed and authorized the shipping and mailing, in interstate commerce, of contaminated methylprednisolone acetate to NECC customers nationwide. Mr. Cadden also caused drugs to be introduced and delivered into interstate commerce without the valid prescription of a practitioner licensed by law to administer drugs, which act resulted in the drugs being misbranded. Further, Mr. Cadden defrauded the United States by interfering with and obstructing the lawful governmental functions of FDA by claiming to be a pharmacy dispensing drugs pursuant to valid, patient-specific prescriptions. In fact, NECC routinely dispensed drugs in bulk without valid, patient-specific prescriptions.

As a result of this conviction, FDA sent Mr. Cadden, by certified mail on June 2, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Cadden was convicted of felonies under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Cadden an opportunity to request a hearing, providing him 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 an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Cadden received the proposal on June 9, 2020. Mr. Cadden did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and 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(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Barry J. Cadden, has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Barry J. Cadden, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Barry J. Cadden, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Cadden provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications from Mr. Cadden during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Cadden for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2019–N–4248 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

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

Dated: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26255 Filed 11–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1255]

Tuan Anh Tran: 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 Tuan Anh Tran 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 Mr. Tran 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. Mr. Tran was given notice of the proposed debarment and an opportunity to request a hearing to show why he should not be debarred. As of September 14, 2020 (30 days after receipt of the notice), Mr. Tran had not responded. Mr. Trans's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is applicable November 30, 2020.

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 FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual 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 personal or household use by the importer), and the shipments are not designated in an entry in an authorized electronic data exchange system as products regulated by FDA.

After an investigation, FDA discovered that Mr. Tran has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action were intercepted by FDA at the John F. Kennedy International Mail Facility and were addressed to Mr. Tran at one of two addresses connected to him.

On or about April 12, 2019, Mr. Tran offered for import three parcels. The product contained in the first parcel was 210 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on May 17, 2019. The product contained in the second parcel was 245 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on May 17, 2019. The product contained in the third parcel was 245 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because the product was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on May 17, 2019.

On or about September 13, 2019, Mr. Tran offered for import four parcels. The product contained in the first parcel was 312 Kamagra Sildenafil Citrate Chewable Tablets and was a misbranded drug because it was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on October 22, 2019. The product contained in the second parcel was 312 Kamagra Sildenafil Citrate Chewable Tablets and was a misbranded drug because it was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on October 22, 2019. The product contained in the third parcel was 196 packets (pieces) of Kamagra Sildenafil Citrate Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on October 22, 2019. The product contained in the fourth parcel was 231 packets (pieces) of Kamagra Sildenafil Citrate Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on October 22, 2019.

On or about September 26, 2019, Mr. Tran offered for import a parcel that was intercepted and processed by FDA. The product contained in the parcel was 196 packets (pieces) of Kamagra Sildenafil Oral Jelly and was a misbranded drug because it was a prescription drug product that failed to contain the ''Rx-only'' symbol on its label. The product was refused entry on October 29, 2019.

Because 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, FDA sent Mr. Tran, by certified mail on August 7, 2020, a notice proposing to debar him for 5 years 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. Tran's pattern of conduct and concluded that his conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Tran of the proposed debarment and offered him an opportunity to request a hearing, providing him 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. Tran received the proposal and notice of opportunity for a hearing on August 15, 2020. Mr. Tran failed to request a hearing within the timeframe prescribed by regulation and, therefore, has 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. Tuan Anh Tran 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 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. Tran is debarred for 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 Mr. Tran is a prohibited act.

Any application by Mr. Tran for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2020–N–1255 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: November 23, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26250 Filed 11–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Recharter for the National Advisory Council on Nurse Education and Practice

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the National Advisory Council on Nurse Education and Practice (NACNEP) has been rechartered. The effective date of the recharter is November 30, 2020.

FOR FURTHER INFORMATION CONTACT: Camillus Ezeike, Ph.D., JD, LLM, RN, PMP, Designated Federal Officer, Bureau of Health Workforce, Division of Nursing and Public Health, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–2866; or *BHWNACNEP@hrsa.gov*.

SUPPLEMENTARY INFORMATION: NACNEP provides advice and recommendations to the Secretary of HHS (''Secretary'') and Congress on policy matters and the preparation of general regulations concerning activities under Title VIII of the Public Health Service (PHS) Act, including the range of issues relating to the nurse workforce, education, and practice improvement. NACNEP also prepares and submits an annual report to the Secretary and Congress describing its activities, including NACNEP's findings and recommendations concerning activities under Title VIII, as required by the PHS Act.

The recharter of NACNEP was approved on November 30, 2020, which will also stand as the filing date. The recharter of NACNEP gives authorization for the Council to operate until November 30, 2022.

A copy of the NACNEP charter is available on the NACNEP website at *https://www.hrsa.gov/advisory-committees/nursing/about.html.* A copy of the charter can also be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–26247 Filed 11–27–20; 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; Information Collection Request Title: Rural Health Care Coordination Program OMB No. 0906–0024—Reinstate With Changes

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 the 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 January 29, 2021.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Rural Health Care Coordination Program OMB No. 0906–0024—Reinstate with Changes.

Abstract: The Rural Health Care Coordination Program (Care Coordination Program) is authorized under Section 330A(e) of the Public Health Service Act (42 U.S.C. 254(e)), as amended, to ''improve access and quality of care through the application of care coordination strategies with the focus areas of collaboration, leadership and workforce, improved outcomes, and sustainability in rural communities.'' This authority permits HRSA's Federal Office of Rural Health Policy to support rural health consortiums/networks aiming to achieve the overall goals of improving access, delivery, and quality of care through the application of care coordination strategies in rural communities.

This ICR was discontinued in January 2020. HRSA is requesting a reinstatement with changes as it was decided to re-compete this pilot program.

The proposed Rural Health Care Coordination Program draft measures for information collection reflect changes to the Clinical Measures section, which was previously in section eight and now currently in section six. The Clinical Measures Section now expands previous project focus from three chronic diseases (*i.e.* Type 2 diabetes, Congestive Heart Failure, and Chronic Obstructive Pulmonary Disease) to an inclusive list of clinical measures in order to reflect a patient's overall health and well-being as well as the organization's overall improved outcomes for the project. Proposed revisions also include measures to examine key elements cited for a successful rural care coordination program: (1) Collaboration, (2) leadership and workforce, (3) improved outcomes, and (4) sustainability.

1. Collaboration—Utilizing a collaborative approach to coordinate and deliver health care services through a consortium, in which member organizations actively engage in integrated, coordinated, patient-centered delivery of health care services.

2. Leadership and Workforce—Developing and strengthening a highly skilled care coordination workforce to respond to vulnerable populations' unmet needs within the rural communities.

3. Improved Outcomes—Expanding access and improving care quality and delivery, and health outcomes through evidence-based model and/or promising practices tailored to meet the local populations' needs.

4. Sustainability—Developing and strengthening care coordination program's financial sustainability by establishing effective revenue sources such as expanded service reimbursement, resource sharing, and/or contributions from partners at the