Dated: February 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04469 Filed 3–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0665]

George Kuiper: 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 George Kuiper 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. Kuiper was convicted of multiple felony offenses: One count of smuggling, one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs, and one count of introduction into interstate commerce of unapproved drugs. The factual basis supporting Mr. Kuiper's convictions, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Kuiper was given notice of the proposed debarment and was given an opportunity to request a hearing to show why he should not be debarred. As of December 8, 2021 (30 days after receipt of the notice), Mr. Kuiper had not responded. Mr. Kuiper'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 March 3, 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 May 26, 2021, Mr. Kuiper was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the District of New Hampshire, when the court entered judgment against him for one count of smuggling in violation of 18 U.S.C. 545; one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs in violation of 18 U.S.C. 371 and 545 and sections 301(d) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(d) and 333(a)(2)); and one count of introduction into interstate commerce of unapproved drugs in violation of sections 301(d) and 303(a)(2) of the FD&C Act. FDA's finding that debarment is appropriate is based on the felony convictions referenced herein.

The factual basis for these convictions is as follows: As contained in the plea agreement in Mr. Kuiper's case, filed on December 21, 2020, from as early as 2006, and until June 2020, Mr. Kuiper operated an internet pharmacy through several websites which changed over the years. Specifically, Mr. Kuiper operated the website *nubrain.com* until February 2015, when the registration for the website was revoked after FDA notified the domain name registrar that the website was selling products in violation of section 301 of the FD&C Act). Mr. Kuiper then immediately re-established his operations on a new website, *healthclown.com*. On both these websites, Mr. Kuiper offered for sale over 100 types of products, including prescription drugs and controlled substances.

Mr. Kuiper's best-selling product through these websites was modafinil, a new prescription drug, and a Schedule IV controlled substance. FDA-approved modafinil, sold under the trade name PROVIGIL, is indicated to improve wakefulness in patients with excessive daytime sleepiness associated with narcolepsy, and it is only available by prescription. The version of modafinil Mr. Kuiper sold was not approved by the FDA, and it is therefore an unapproved new drug. FDA's Office of Criminal Investigations (OCI) conducted a number of controlled buys of unapproved modafinil and other unapproved prescription drugs from Mr. Kuiper's websites over approximately 11 years. On most occasions, the drugs were either received by OCI directly from shippers in foreign countries or had packaging indicating that they were manufactured in foreign countries. During subsequent interviews, Mr. Kuiper admitted to investigators that he caused unapproved modafinil to be shipped directly to customers from his overseas suppliers. OCI's purchases from Mr. Kuiper's websites never required a prescription.

As a result of his convictions, FDA sent Mr. Kuiper, by certified mail on October 28, 2021, a notice proposing to debar him 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 Mr. Kuiper's convictions for three felony counts under Federal law, specifically for one count of smuggling, one count of conspiracy to smuggle goods into the United States and to introduce into interstate commerce unapproved drugs, and one count of introduction into interstate commerce of unapproved drugs, were for conduct relating to the importation into the United States of any drug or controlled substance, because he knowingly conspired to illegally smuggle modafinil, an unapproved drug and controlled substance, into the United States on multiple occasions and then caused it to be introduced into interstate commerce.

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. Kuiper's offenses and concluded that each felony offense warranted the imposition of a 5-year period of debarment. However, FDA placed significant weight on the cooperation Mr. Kuiper provided to law enforcement. Specifically, upon the execution of a search warrant by FDA's OCI, Mr. Kuiper immediately began to cooperate meaningfully with Federal agents and ceased his own operations.

In light of Mr. Kuiper's assistance, FDA determined that the 5-year debarment periods for each conviction should run concurrently. The proposal informed Mr. Kuiper of the proposed debarment, 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. Kuiper

received the proposal and notice of opportunity for a hearing on November 8, 2021. Mr. Kuiper 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)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. George Kuiper has been convicted of felonies under Federal law for conduct relating to the importation into the United States of any drug or controlled substance. FDA finds that the offenses 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. Kuiper is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (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. Kuiper is a prohibited act.

Any application by Mr. Kuiper for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0665 and sent to the Dockets Management Staff (see **ADDRESSSES**). 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: February 25, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04484 Filed 3–2–22; 8:45 am]

BILLING CODE 4146–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2021–N–0918; FDA–2018–N–1967; FDA–2009–D–0268; and FDA–2019–N–3077]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Labeling Requirements for Human Prescription Drug and Biological Products	0910–0572	1/31/2025
Biosimilar User Fee Program	0910–0718	1/31/2025
Labeling of Certain Beers Subject to the Labeling Jurisdiction of the FDA	0910–0728	1/31/2025
Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities	0910–0883	2/28/2025

Dated: February 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–04409 Filed 3–2–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0117]

Agency Information Collection Activities; Proposed Collection; Comment Request; Authorization for Medical Products for Use in Emergencies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA Authorization for Medical Products for Use in Emergencies.

DATES: Submit either electronic or written comments on the collection of information by May 2, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 2, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 2, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.