into the docket on June 8, 2021, both from his case, Mr. Navarro was an advanced Registered Nurse Practitioner employed as a sub-investigator at Tellus Clinical Research (Tellus) under the direction of a clinical investigator. Tellus was a medical clinic that conducted clinical trials on behalf of pharmaceutical company sponsors. A drug manufacturer (Sponsor) initiated a clinical trial concerning a new investigational drug intended to treat patients suffering from irritable bowel syndrome (Study or IBS Trial). The Sponsor retained a Contract Research Organization (CRO) to manage various aspects of the IBS Trial. The CRO entered into a contract with Tellus and Martin Valdes, a medical doctor serving as a clinical investigator for clinical trials conducted at Tellus and as the clinical investigator for the IBS Trial. The study protocol for the IBS trial required subjects to make periodic scheduled visits to the clinical trial site for which they were paid $100 per visit. During some of these visits, subjects were required to provide blood samples for pharmacokinetic analysis, receive physical exams by clinical trial staff, and undergo electrocardiograms. Subjects were also required to use an ''e-diary'' system to report their daily experience with the Study drugs. They would do this by making daily phone calls to a number maintained by a third party and answering automated questions nonverbally by touch-tone buttons.

In his role as a sub-investigator, Mr. Navarro was responsible for conducting physical exams on subjects, reviewing lab work and electrocardiograms, and preparing case histories reflecting the participation of subjects in the Study. However, Mr. Navarro and his co-conspirators engaged in an effort to impair, impede, and obstruct FDA's legitimate function of regulating clinical trials of drugs in order to obtain money. Mr. Navarro and his co-conspirators did this by fabricating medical records to portray persons as legitimate Study subjects when they were not. He and his co-conspirators falsified these records to make it appear that the Study subjects had consented to participating in the Study, satisfied the Study's eligibility criteria, appeared for scheduled visits at the Study's site, taken Study drugs as required, and received checks as payment for site visits, among other things. For example, Mr. Navarro represented that he had seen a purported Study subject and performed a physical examination of her when he knew she was not a Study subject and these representations were false. Mr. Navarro also knew that one or more of his co-conspirators placed telephone calls to the e-diary system for the purposes of reporting fabricated data on behalf of purportedly legitimate Study subjects.

As a result of this conviction, FDA sent Mr. Navarro by certified mail on November 8, 2021, 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)(A) of the FD&C Act, that Mr. Navarro was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Mr. Navarro 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. Navarro received the proposal on November 24, 2021. He 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)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Navarro has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Navarro is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see section 306(a)(2)(A) and (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 Mr. Navarro 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. Navarro 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 application from Mr. Navarro during his period of debarment, other than in connection with an audit under section 306(c)(1)(B) of the FD&C Act. Note that, for purposes of sections 306 and 307 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, or 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. Navarro for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0964 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 (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. 2022–04459 Filed 3–2–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0873]

Patrick Charles Bishop: 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 Patrick Charles Bishop 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. Bishop was convicted of one felony count under Federal law for conspiracy to commit fraud. The factual basis supporting Mr. Bishop's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Bishop was given notice of the proposed

debarment and was given an opportunity to request a hearing to show why he should not be debarred. Mr. Bishop provided notice to FDA that he acquiesced to the debarment; FDA received that notice on January 4, 2022. As such, his debarment commenced on the date FDA was notified of acquiescence.

DATES: This order is applicable January 4, 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 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 July 9, 2021, Mr. Bishop was convicted, as defined in section 306(l)(1) of FD&C Act, in the U. S. District Court for the Northern District of Alabama, when the court entered judgment against him for the offense of conspiracy to commit fraud, in violation of 18 U.S.C. 371.

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 plea agreement in Mr. Bishop's case, filed on January 7, 2021, in which he pleaded guilty, he owned Patrick, LLC and employed other individuals. Using the business name ''Best Peptide Supply, LLC,'' he ordered PNC–27 from GL Biochem (Shanghai), Ltd., a supplier based in China, and used the PNC–27 to manufacture drug products intended for the treatment of cancer in humans. FDA has not approved PNC–27 for use in the United States as a drug to treat any disease, including any form of cancer. He obtained PNC–27 under the false pretense that he intended to use the product solely for laboratory research purposes. In fact, he provided invoices to GL Biochem that did not use the term ''PNC–27'' and included the statement ''FOR RESEARCH ONLY.'' He falsely certified to GL Biochem that the product he was purchasing from GL Biochem was ''restricted to laboratory research purposes, excluding clinical research on [the] human body.''

Mr. Bishop also falsely represented to FDA personnel that the product shipped from GL Biochem was to be used for laboratory testing and scientific research. Mr. Bishop directed GL Biochem to ship the PNC–27 to his residences and other locations in the State of Alabama where he used the PNC–27 he purchased to manufacture drug products intended for human use to treat cancer. Specifically, along with others, Mr. Bishop knowingly caused PNC–27 to be processed into a ''water-based PNC–27 drug product'' as well as suppositories using methods, controls, and facilities that did not conform to current good manufacturing practice. Mr. Bishop sold and distributed the unapproved, misbranded, and adulterated PNC–27 drug products he manufactured to individuals in other States and countries; these drug products failed to bear directions for use, and some bore no labeling whatsoever. To avoid detection by FDA and to conceal the nature of these unapproved, misbranded, and adulterated drug products, Mr. Bishop operated under the business name ''Immuno Cellular Restoration Program, Inc. (ICRP)'' and used the terms, ''research,'' ''sample,'' ''ICRP'' and ''ICRPstudy.com'' on his product labels and shipping documentation. Mr. Bishop received millions of dollars in payments for his unapproved, misbranded, and adulterated PNC–27 drug products.

As a result of this conviction, FDA sent Mr. Bishop, by certified mail, on October 18, 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. Bishop's felony conviction for one count of conspiracy to commit fraud was for conduct relating to the importation into the United States of any drug or controlled substance because he conspired to illegally import, manufacture, and distribute in interstate commerce unapproved, misbranded, and adulterated drug products while concealing this conduct from Federal authorities in violation of 18 U.S.C. 371. 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. Bishop's offense and concluded that the felony offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Bishop 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. Bishop received the proposal and notice of opportunity for a hearing on October 25, 2021. Mr. Bishop sent a memorandum to FDA, dated November 3, 2021, wherein he stated that he acquiesced to the proposed debarment. FDA received the memorandum on January 4, 2022. In accordance with section 306(c)(2)(B) of the FD&C Act, Mr. Bishop's period of debarment shall commence on the date FDA received notice he acquiesced to the debarment, which was January 4, 2022 (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. Patrick Charles Bishop 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, Mr. Bishop is debarred for a period of 5 years from importing or offering for import any drug into the United States, effective January 4, 2022. 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. Bishop is a prohibited act.

Any application by Mr. Bishop for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2021–N–0873 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: 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