



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-3369]

Adam Michael Nagy: 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 (the FD&C Act) debaring Adam Michael Nagy for a period of 15 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Mr. Nagy was convicted of three relevant felony counts under Federal law. The factual basis supporting Mr. Nagy's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Nagy 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 October 22, 2023 (30 days after receipt of the notice), Mr. Nagy had not responded. Mr. Nagy's failure to respond and request a hearing constitutes a waiver of his right to a hearing concerning this matter.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Any application by Mr. Nagy for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted as follows:

Electronic Submissions

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. An application submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your

application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on <https://www.regulations.gov>.

- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All applications must include the Docket No. FDA-2023-N-3369. Received applications will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly 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.

- Confidential Submissions--To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of

your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240-402-8743, or 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 1, 2023, Mr. Nagy was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Western District of Pennsylvania, when the court entered judgment against him for multiple offenses he pled guilty to, including the offenses of: (1)

importation into the United States a quantity of ethylone, a Schedule I Controlled Substance in violation of 21 U.S.C. 952(a) and 960(a)(1); (2) importation into the United States quantities of TURINABOL and DIANABOL, anabolic steroids, and Schedule III Controlled Substances in violation of 21 U.S.C. 952(b) and 960(a)(1); and (3) smuggling goods into the United States, that is, alpha-PVP ethylone, Schedule I Controlled Substances, and TURINBOL and DIANABOL, Schedule III Controlled Substances, 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 superseding indictment, filed on March 22, 2018, the Defendant's motion for downward variance, filed on April 24, 2023, and the Government's sentencing memorandum, filed April 24, 2023, from Mr. Nagy's case, Mr. Nagy was the owner and operator of Prescription Nutrition, Prescription Protein, and N.O.B. Industries located in Pennsylvania. From on or about June 2014 to on or about September 2014, Mr. Nagy imported various types of controlled substances which he then capsuled and distributed to clients. Specifically, from on or about June 2014 to on or about July 2014, Mr. Nagy illegally imported ethylone. In July 2014, he also illegally imported TURINABOL and DIANABOL. In addition, from June 2014 until on or about September 2014, Mr. Nagy illegally imported alpha-PVP, ethylone, TURINABOL, and DIANABOL. All the controlled substances Mr. Nagy imported and smuggled into the country came from China.

As a result of this conviction, FDA sent Mr. Nagy, by certified mail, on September 20, 2023, a notice proposing to debar him for a 15-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. Nagy's three felony convictions that included: (1) importation into the United States a quantity of ethylone, a Schedule I Controlled Substance in violation of 21 U.S.C. 952(a) and 960(a)(1); (2) importation into the United States quantities of TURINABOL and DIANABOL, anabolic steroids and Schedule III Controlled Substances in violation of 21

U.S.C. 952(b) and 960(a)(1); and (3) smuggling goods into the United States, that is, alpha-PVP ethylone, Schedule I Controlled Substances, and TURINBOL, DIANABOL, Schedule III Controlled Substances in violation of 18 U.S.C. 545, were for conduct relating to the importation into the United States of any drug or controlled substance because he imported controlled substances into the United States in order to capsule portions of the drugs to sell to clients. 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. Nagy's offenses and concluded that each offense warranted the imposition of a 5-year period of debarment, to run consecutively, for a total of a 15-year period of debarment.

The proposal informed Mr. Nagy 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. Nagy received the proposal and notice of opportunity for a hearing on September 22, 2023. Mr. Nagy 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 Adam Michael Nagy been convicted of three felonies 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 15 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Mr. Nagy is debarred for a period of 15 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 by, with the assistance of, or at the direction of Mr. Nagy is a prohibited act.

Dated: December 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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