

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than January 18, 2022.

A. *Federal Reserve Bank of New York* (Ivan Hurwitz, Senior Vice President) 33 Liberty Street, New York, New York 10045-0001. Comments can also be sent electronically to

[Comments.applications@ny.frb.org](mailto:Comments.applications@ny.frb.org):

1. *AIB Group, p.l.c., Dublin, Ireland*; to retain GANMAC Holdings (BVI) Limited, and thereby indirectly retain Goodbody Securities, Inc., both of Dublin, Ireland, and engage in securities brokerage activities pursuant to section 225.28(b)(7)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 28, 2021.

**Michele Taylor Fennell**,

*Deputy Associate Secretary of the Board.*

[FR Doc. 2021-28462 Filed 1-3-22; 8:45 am]

**BILLING CODE P**

## GOVERNMENT ACCOUNTABILITY OFFICE

### Request for Medicaid and CHIP Payment and Access Commission (MACPAC) Nominations

**AGENCY:** U.S. Government Accountability Office (GAO).

**ACTION:** Request for letters of nomination and resumes.

**SUMMARY:** The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) established MACPAC to review Medicaid and CHIP access and payment policies and to advise Congress on issues affecting Medicaid and CHIP. CHIPRA gave the Comptroller General of the United States responsibility for appointing MACPAC's

members. GAO is now accepting nominations for MACPAC appointments that will be effective May 2022.

Nominations should be sent to the email address listed below. Acknowledgement of receipt will be provided within a week of submission.

**DATES:** Letters of nomination and resumes should be submitted no later than January 27, 2022, to ensure adequate opportunity for review and consideration of nominees prior to appointment.

**ADDRESSES:** Submit letters of nomination and resumes to [MACPACappointments@gao.gov](mailto:MACPACappointments@gao.gov).

**FOR FURTHER INFORMATION CONTACT:** Susan Anthony at (312) 220-7666 or [anthony@gao.gov](mailto:anthony@gao.gov) if you do not receive an acknowledgment or need additional information. For general information, contact GAO's Office of Public Affairs, (202) 512-4800.

(Authority: Pub. L. 111-3, sec. 506; 42 U.S.C. 1396.)

**Gene L. Dodaro**,

*Comptroller General of the United States.*

[FR Doc. 2021-27494 Filed 1-3-22; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0506]

#### William Kulakevich: 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 William Kulakevich 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. Kulakevich was convicted of one felony count under Federal law for conspiracy to commit offenses against the United States. The factual basis supporting Mr. Kulakevich's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Kulakevich 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 September 16, 2021 (30 days after receipt of the notice), Mr. Kulakevich had not responded. Mr. Kulakevich'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 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](mailto: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 23, 2019, Mr. Kulakevich 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 the offense of conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 2 and 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 indictment in Mr. Kulakevich's case, filed August 22, 2017, to which he plead guilty, from on or about April 2015, and continuing until May 2017, Mr. Kulakevich was the owner and a co-operator of a website, [www.etizy.com](http://www.etizy.com), through which he sold and distributed a drug known as etizolam to consumers throughout the United States. Etizolam is a drug known as thienodiazepine, which is chemically similar to benzodiazepines and carries risks of dependency, toxicity, and the possibility of fatal overdose. Etizolam is not FDA-approved in the United States. Mr. Kulakevich and his co-conspirator illegally bought etizolam from an overseas supplier in India, after which he arranged to have it smuggled into the United States through the use of multiple post office boxes controlled by him and his coconspirator. To avoid Federal regulators, Mr. Kulakevich used

false and misleading labeling and generally misrepresented the nature of the products sold on his website. Mr. Kulakevich reshipped the misbranded etizolam to customers located in the United States.

As a result of this conviction, FDA sent Mr. Kulakevich, by certified mail, on August 3, 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. Kulakevich's felony conviction under Federal law for conspiracy to commit offenses against the United States, in violation of 18 U.S.C. 2 and 371, was for conduct relating to the importation into the United States of any drug or controlled substance because he illegally imported, relabeled, and then introduced unapproved etizolam products 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. Kulakevich's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Kulakevich 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. Kulakevich received the proposal and notice of opportunity for a hearing on August 17, 2021. Mr. Kulakevich 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. William Kulakevich 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. Kulakevich 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 Mr. Kulakevich is a prohibited act.

Any application by Mr. Kulakevich for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-0506 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: December 28, 2021.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2021-28479 Filed 1-3-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-1353]

#### Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on February 15, 2022, from 9:30 a.m. to 5 p.m. Eastern Time.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this

advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-1353. The docket will close on February 14, 2022. Submit either electronic or written comments on this public meeting by February 14, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 14, 2022. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 14, 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.

Comments received on or before February 1, 2022, will be provided to the committees. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

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

- If you want to submit a comment with confidential information that you do not wish to be made available to the