U.S. FOOD & DRUG ADMINISTRATION

April 3, 2025

Steve Back
Chief Operating Officer
Nuclein, LLC
8305 Cross Park Drive
Austin, TX 78754
Re: Revocation of EUA210603

Dear Steve Back:

This letter is in response to the request from Nuclein, LLC (following Nuclein, LLC's December 27, 2024, merger with, and assumption of responsibility for, the original EUA holder, Minute Molecular Diagnostics, Inc.), in a letter dated March 17, 2025, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the DASH SARS-CoV-2/S Test issued on March 15, 2022, and amended on July 28, 2022. Nuclein, LLC indicated that they have ceased manufacture of the authorized product and requested that the EUA be revoked. FDA understands that as of the date of this letter there are no viable DASH SARS-CoV-2/S Test reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Nuclein, LLC has requested that FDA revoke the EUA for the DASH SARS-CoV-2/S Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA210603 for the DASH SARS-CoV-2/S Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the DASH SARS-CoV-2/S Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09678 Filed 5–28–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5302]

Michael Dominic Diaz: 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 Michael Dominic Diaz 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. Diaz was convicted of one felony count under Federal law. The factual basis supporting Mr. Diaz's conviction, as described below, is conduct relating

to the importation into the United States of a drug or controlled substance. Mr. Diaz 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 May 16, 2024 (30 days after receipt of the notice), Mr. Diaz had not responded. Mr. Diaz'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 May 29, 2025.

ADDRESSES: Any application by Mr. Diaz for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–5302. 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, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Field Enforcement, Office of Field Regulatory Operations, Office of Inspections and Investigations, Food and Drug Administration, 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 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 November 27, 2023, Mr. Diaz was convicted as defined in section 306(l)(1) of the FD&C Act in the U.S. District Court for the Western District of Texas-San Antonio Division when the court accepted his plea of guilty and entered judgment against him for the felony offense of Conspiracy to Defraud the United States and Violate 21 U.S.C. 331—Introduction of Misbranded Drugs into Interstate Commerce in violation of 18 U.S.C. 371. The underlying facts supporting the conviction are as follows: As contained in the Information from his case, beginning no later than August 2019 and continuing to on or about June 2022, Mr. Diaz was involved in the operation of multiple businesses and associated websites, including Proximo Research and Gulf Coast Chems. The websites for these businesses allowed end consumers to place orders for misbranded prescription drugs, which would be shipped to them via the U.S. Postal Service and other common carriers. The websites offered various drugs for sale, including Clonazolam, Flubromazolam, Fluclotizolam, O-Desmethyl-cis-tramadol (ODSMT) and 2-Methyl-AP-237 (2MAP); these drugs are not approved by FDA for any use in the United States and, during the time Mr. Diaz was involved in operating the Proximo Research and Gulf Coast Chems websites, were not controlled under the Controlled Substances Act. At least some of the drugs offered on the websites for these businesses were purchased by Mr. Diaz, and others, in bulk quantities from sellers located outside the United States, primarily from China. Once orders were placed through the websites, Mr. Diaz, assisted by others, would repackage the drugs into consumer-size containers and ship them to customers at various locations throughout the United States. Mr. Diaz did not require evidence or submission of lawful prescriptions before accepting payment for and shipping the drugs. Despite Mr. Diaz's awareness that individuals were buying the drugs for personal use, he misbranded the drugs being sold with disclaimers that they were ''for research purposes only'' and ''not for human consumption'' in an attempt to evade FDA's regulatory oversight and authority.

FDA sent Mr. Diaz, by certified mail, on April 10, 2024, 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. Diaz's felony conviction under Federal law for conspiracy to defraud

the United States and Violate 21 U.S.C. 331—Introduction of Misbranded Drugs into Interstate Commerce in violation of 18 U.S.C. 371, was for conduct relating to the importation of any drug or controlled substance into the United States because Mr. Diaz illegally imported unapproved drugs from sellers located outside of the United States, including in China, and introduced misbranded drug 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. Diaz's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Diaz 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. Diaz received the proposal and notice of opportunity for a hearing on April 16, 2024. Mr. Diaz 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 Division of Field Enforcement, Office of Inspections and Investigations, under section 306(b)(3)(C) of the FD&C Act, under authority delegated to the Director, Division of Enforcement, finds that Mr. Michael Dominic Diaz 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. Diaz 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 by, with the assistance of, or at the direction of Mr. Diaz is a prohibited act.

Dated: May 22, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–09649 Filed 5–28–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5056]

Justin Cole Henry: 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 Justin Cole Henry 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. Henry was convicted of a felony under Federal law for possession with intent to distribute a Schedule III controlled substance. The factual basis supporting Mr. Henry's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Henry 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 February 24, 2025 (30 days after receipt of the notice), Mr. Henry had not responded. Mr. Henry'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 May 29, 2025.

ADDRESSES: Any application by Mr. Henry for termination of debarment under section 306(d)(1) of the FD&C Act (21 U.S.C. 335a(d)(1)) may be submitted at any time 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–2024–N–5056. 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.*

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