On page 42203, in the second column, the **ADDRESSES** portion of the document is changed to read as follows: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On page 42204, in the second column, the **SUPPLEMENTARY INFORMATION**: *Procedure* portion of the document is changed to read as follows: Oral presentations from the public will be scheduled between approximately 12:35 p.m. and 2:05 p.m. Eastern Time.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15017 Filed 7–23–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–6771]

Cellular, Tissue, and Gene Therapies Advisory Committee; Amendment of Notice—Biologics License Application (BLA) 125842 From Capricor, Inc. for Deramiocel (Human Allogeneic Cardiosphere-Derived Cells)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). This meeting was announced in the **Federal Register** on June 29, 2026. The amendment is being made to reflect a change in the **DATES**, **ADDRESSES**, and **SUPPLEMENTARY INFORMATION**: *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Cicely Reese; Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3215, Silver Spring, MD 20993–0002, 301–796–9025, email: *CBERCTGTAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 29, 2026, meeting notice and citation, 91 FR 39101, FDA announced that a meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee would be held on July 29, 2026. On page 39101, in the third column, the **DATES** portion of the document is changed to read as follows:

The meeting will be held on July 29, 2026, from 9:30 a.m. to 4:50 p.m. Eastern Time. Online public viewing will be available at the following link on the day of the meeting at: *https://youtube.com/live/SUNn6YcBhnw?feature=share.*

On page 39101, in the third column, the **ADDRESSES** portion of the document is changed to read as follows: The meeting will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. The public will also have the option to participate, and the advisory committee meeting will be heard, viewed, captioned, and recorded through an online teleconferencing and/or video conferencing platform. On page 39102, in the third column, the **SUPPLEMENTARY INFORMATION**: *Procedure* portion of the document is changed to read as follows: Oral presentations from the public will be scheduled between approximately 12:05 p.m. and 1:35 p.m. Eastern Time.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15016 Filed 7–23–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1199]

Francis Esteban Matos: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Francis Esteban Matos 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. Matos was convicted of a felony under Federal law. The factual basis supporting Mr. Matos's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Mr. Matos 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 18, 2026 (more than 30 days after receipt of the notice), Mr. Matos had not responded. Mr. Matos'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 July 24, 2026.

ADDRESSES: Any application by Mr. Matos 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–2026–N–1199. 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. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' 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 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 October 14, 2025, Mr. Matos was convicted as defined in section 306(l)(1) of the FD&C Act, in the U.S. District Court for the Eastern District of Pennsylvania, when the court accepted his plea of guilty and entered judgment against him for the felony offense of conspiracy to introduce 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, to which he pleaded guilty, Mr. Matos operated a business called Suplidora America that, among other things, obtained and distributed pharmaceutical drugs even though neither Mr. Matos nor Suplidora America had a license to obtain, hold, or dispense pharmaceutical drugs.

Beginning in or about May 2022, Mr. Matos arranged to have others purchase pharmaceutical drugs in the Dominican Republic and mail them to him and his associates. On various occasions between in or about May 2022 and in or about January 2023, law enforcement seized parcels containing pharmaceutical drugs sent from the Dominican Republic to Mr. Matos and his associates. Some of these parcels contained tablets containing sildenafil. At times, Mr. Matos received notification from law enforcement that parcels sent to him containing pharmaceutical drugs had been seized by law enforcement. Mr. Matos and his associates would then sell the pharmaceutical drugs to customers, typically convenience stores. Mr. Matos did not require his customers to provide a prescription to obtain pharmaceutical drugs from him or Suplidora America even though many of the pharmaceutical drugs dispensed by him and his associates required such a prescription. The drugs Mr. Matos introduced into interstate commerce were misbranded because (1) the drugs' labeling failed to bear adequate directions for use as required by section 502(f) of the FD&C Act (21 U.S.C. 352(f)); (2) the drugs' labeling was in a foreign language (Spanish), in violation of section 502(c) of the FD&C Act; and (3) the drugs were dispensed without the prescription of a practitioner licensed by law to administer such drugs in violation of sections 503(b), 301(a), and 303(a)(2) of the FD&C Act (21 U.S.C. 353(b), 331(a), and 333(a)(2)).

FDA sent Mr. Matos, by certified mail, on April 13, 2026, 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. Matos's felony conviction under Federal law for conspiracy to introduce 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. Matos conspired to illegally import and introduce misbranded prescription 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 the Agency considered applicable to Mr. Matos's offense and concluded that the offense warranted the imposition of a 5-year period of debarment.

The proposal informed Mr. Matos 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 a waiver of any contentions concerning this action. Mr. Matos received the proposal and notice of opportunity for a hearing on April 16, 2026. Mr. Matos 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 Director, 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. Francis Esteban Matos 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. Matos 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, the importing or offering for import into the United States of any drug by, with the assistance of, or at the direction of Mr. Matos during his period of debarment is a prohibited act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14989 Filed 7–23–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HHS Request for Comment on the Update to the National Plan To Address Alzheimer's Disease

AGENCY: U.S. Department of Health and Human Services (HHS or the Department).

ACTION: Notice of Request for Information (RFI) to inform a comprehensive update to the National Plan to Address Alzheimer's Disease.

SUMMARY: HHS released the first National Plan to Address Alzheimer's Disease in 2012, establishing a comprehensive framework to accelerate scientific progress and improve support for individuals living with Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD) and their families. Since then, the National Plan has been updated annually and has guided federal efforts across research, care delivery, public health, and data infrastructure. HHS is now updating the overall National Plan to lead federal efforts through 2035. HHS would like input from the public to inform the future direction of federal efforts. Through this RFI, HHS invites public comment on approaches to advancing AD/ADRD research and development of new interventions to prevent and treat dementia, risk reduction strategies, early detection and diagnostic tools, and/or enhanced care, services, and supports for people living with dementia and their families, caregivers, and care partners. The Department also seeks input on gaps, emerging priorities, and opportunities to strengthen coordination across federal, state, Tribal, local, private sector, and community partners.

The purpose of this RFI is to solicit public input to inform the development of a comprehensive update to the National Plan to Address Alzheimer's Disease, including future goals and priorities.

DATES: Comments on this notice must be received by August 15, 2026.

ADDRESSES: *RFI Docket:* You may examine the RFI docket at *regulations.gov* under HHS–ASPE–2026–0298. The docket contains this RFI and all comments received to date. To submit a response, click the ''Comment'' button inside Docket: HHS–ASPE–2026–0298 and follow all instructions.

FOR FURTHER INFORMATION CONTACT: Maria-Theresa Okafor, Ph.D., MCG, Office of the Assistant Secretary for Planning and Evaluation (ASPE), 771–223–7102 or by email at: *maria-theresa.okafor@hhs.gov.*

SUPPLEMENTARY INFORMATION: The National Alzheimer's Project Act (NAPA) (Public Law 111–375) was passed by Congress in 2010 and signed into law on January 4, 2011, in recognition of the growing impact of AD/ADRD on the American public. NAPA requires the Secretary of HHS to create and maintain a coordinated national strategy to address AD/ADRD, including advancing research, improving care and services, and enhancing public awareness. The National Plan to Address Alzheimer's Disease serves as the nation's blueprint for achieving the vision of a nation free of AD/ADRD. Congress and federal partners have supported significant advancements in Alzheimer's disease research, care models, and public health infrastructure. These efforts have contributed to meaningful progress in scientific discovery, increased public awareness, and expanded supports for people living with dementia and their caregivers. To sustain and build on this progress, Congress enacted the NAPA Reauthorization Act (Public Law 118–92) on October 1, 2024, extending the federal commitment to addressing AD/ADRD over the next decade. HHS will undertake a comprehensive update of the National Plan in 2026 to identify emerging priorities and future goals with a focus on AD/ADRD research and development of new interventions to prevent and treat dementia, risk reduction strategies, early detection and diagnostic tools and pathways to treatment, and enhanced long-term services and supports for people living with AD/ADRD and their caregivers and care partners.

Request for Information

For this RFI, HHS is seeking input from the public, including individuals living with AD/ADRD, caregivers, researchers, clinicians, service providers, advocates, faith- and community- based organizations, state, Tribal, and local officials, policymakers and other interested stakeholders. Respondents are encouraged to include supporting facts, research, and evidence in their comments, including citations to the published materials referenced, and active hyperlinks, where available. The questions below are of particular interest.

This RFI should not be construed as a policy, solicitation for applications, or as an obligation on the part of the government to provide support for any ideas in response to it. HHS will use the information submitted in response to this RFI at its discretion and will not provide comments on any respondent's submission. However, responses to this RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports.

Instructions

Responses submitted at *regulations.gov/deregulation* should follow the format provided there. You may respond to one or more of the questions listed below and please include question numbers provided in the response. Each responding entity (person or organization) is requested to submit only one response. Unless submitted anonymously, responses should include the name(s) of the person(s) or organization(s) submitting the comment. If a comment is submitted on behalf of an organization, the individual respondent's role in the organization may also be provided.

This RFI is voluntary, and responses may be submitted anonymously. Comments submitted in response to this RFI may be posted on HHS websites or otherwise released publicly. Please do not submit proprietary, classified, confidential, or sensitive information, to include personally identifiable (PII) or personal health information (PHI), in response to this RFI.

This RFI is for information and planning purposes only and should not be construed as a policy, solicitation for applications, or as an obligation on the part of the government to provide support for any ideas in response to it. HHS will use the information submitted at its discretion and will not comment on any respondent's submission. However, responses to this RFI may be reflected in future solicitation(s) or policies. The information provided will be analyzed and may appear in reports. Respondents are advised that the government is not obligated to acknowledge receipt of submissions. Those submitting responses are solely responsible for all expenses associated with response preparation.