



December 2, 2022

Beth Lingenfelter
VP of Clinical and Regulatory Affairs
Visby Medical, Inc.
3010 North First Street
San Jose, CA 95134

Re: Revocation of EUA203089

Dear Ms. Lingenfelter:

This letter is in response to the request from Visby Medical, Inc., received via email on November 29, 2022, that the U.S. Food and Drug Administration (FDA) close the EUA for the Visby Medical COVID-19 Point of Care Test issued on February 8, 2021, amended on September 23, 2021, and reissued on July 22, 2022. Visby Medical, Inc. discontinued manufacturing the Visby Medical COVID-19 Point of Care Test on April 25, 2022, and FDA understands there are no viable (non-expired) Visby Medical COVID-19 Point of Care Tests 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 Visby Medical, Inc. has requested FDA close the EUA for the Visby Medical COVID-19 Point of Care Test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203089 for the Visby Medical COVID-19 Point of Care Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Visby Medical COVID-19 Point of Care 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/

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Dated: December 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-28496 Filed 12-30-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of First Meeting of the 2025 Dietary Guidelines Advisory Committee and Request for Comments

AGENCY: U.S. Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health (OASH); U.S. Department of Agriculture (USDA),

Food, Nutrition, and Consumer Services (FNCS).

ACTION: Notice.

SUMMARY: The U.S. Departments of Health and Human Services and Agriculture announce the first meeting of the newly appointed 2025 Dietary Guidelines Advisory Committee (Committee). This meeting will be open to the public virtually. Additionally, this notice opens a public comment period that will remain open until late 2024, throughout the Committee's deliberations.

DATES: The first meeting will be held February 9–10, 2023. The public

comment period opens with the publication of this notice.

ADDRESSES:

(a) The meeting will be accessible online via livestream and recorded for later viewing. Registrants will receive the livestream information prior to the meeting.

(b) You may send comments, identified by Docket OASH–2022–0021, by either of the following methods:

- *Online (preferred method):* Federal eRulemaking Portal: <http://www.regulations.gov>.
- *Mail:* Janet M. de Jesus, MS, RD, HHS/OASH Office of Disease Prevention and Health Promotion

(ODPHP), 1101 Wootton Parkway, Suite 420, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket OASH–2022–0021. For detailed instructions on sending comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Designated Federal Officer, 2025 Dietary Guidelines Advisory Committee, Janet M. de Jesus, MS, RD; HHS/OASH/ODPHP, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240–453–8266; Email DietaryGuidelines@hhs.gov. Additional information is available on the internet at www.DietaryGuidelines.gov.

SUPPLEMENTARY INFORMATION:

Authority and Purpose: Under section 301 of Public Law 101–445 (7 U.S.C. 5341, the National Nutrition Monitoring and Related Research Act of 1990, Title III), the Secretaries of HHS and USDA are directed to publish the *Dietary Guidelines for Americans* (*Dietary Guidelines*) jointly at least every five years. The law instructs that this publication shall contain nutritional and dietary information and guidelines for the general public; shall be based on the preponderance of scientific and medical knowledge current at the time of publication; and shall be promoted by each Federal agency in carrying out any Federal food, nutrition, or health program. The current edition of the *Dietary Guidelines* (2020–2025) provides guidance on the entire lifespan, from birth to older adulthood, including pregnancy and lactation. The *Dietary Guidelines for Americans, 2025–2030* will continue to provide food-based dietary guidance across the entire lifespan to help meet nutrient needs, promote health, and reduce the risk of chronic disease. HHS and USDA appointed the 2025 Dietary Guidelines Advisory Committee (Committee) to conduct an independent scientific review that will help inform the Departments' development of the next edition of the *Dietary Guidelines*. The Committee's review and advice will focus on the scientific questions prioritized by HHS and USDA, with the potential to inform nutrition guidance for Americans across the lifespan. Information on the 2025 Committee membership and the scientific questions will be available at www.DietaryGuidelines.gov.

The 2025 Committee's formation is governed under the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app), which sets

forth standards for the formation and use of advisory committees.

Committee's Task: The work of the Committee will be solely advisory in nature and time limited. The Committee will examine evidence on the scientific questions, using approaches including systematic reviews, food pattern modeling, and data analysis. The Committee will then develop a scientific report to be submitted to the HHS and USDA Secretaries. The scientific report should describe the Committee's review and conclusions and provide science-based advice and rationale to the Departments based on the preponderance of evidence reviewed. HHS and USDA will consider the Committee's scientific report as they develop the *Dietary Guidelines for Americans, 2025–2030*. The Committee will hold approximately six meetings, open to the public virtually, to review the evidence and discuss recommendations. Future meeting dates, times, and other relevant information will be announced via **Federal Register** notice and at www.DietaryGuidelines.gov. As stipulated in the charter, the Committee will disband after delivery of its final report to the Secretaries of HHS and USDA, or two years from the date the charter was filed, whichever comes first.

Purpose of the Meeting: In accordance with FACA, and to promote transparency of the process, deliberations of the Committee will occur in a public forum. The purpose of this first meeting is to orient the Committee to the *Dietary Guidelines* process and mark the beginning of its work.

Meeting Agenda: The first meeting agenda will include (a) review of operations for the Committee members, (b) overview of the proposed scientific questions identified by the Departments to be examined by the Committee, (c) presentations on the evidence-based approaches for reviewing the scientific evidence, and (d) plans for future Committee work.

Meeting Registration: The meeting is open to the public. The meeting will be accessible online via livestream and recorded for later viewing. Registration is required for the livestream. To register, go to www.DietaryGuidelines.gov and click on the link for "Meeting Registration." Online registration begins on January 18, 2023 and ends on February 10, 2023. To request a sign language interpreter or other special accommodations, please email diaryguidelines@hhs.gov by February 5, 2023. All registrants will be asked to provide their name, affiliation, email address, and days attending. After

registration, individuals will receive livestream access information via email.

Public Comments and Meeting

Documents: Written comments from the public will be accepted throughout the Committee's deliberative process for the next approximately two years.

Opportunities to present oral comments to the Committee will be provided at a future meeting.

- **Online (preferred method):** Follow the instructions for submitting comments at www.regulations.gov. Comments submitted electronically, including attachments, will be posted to Docket OASH–2022–0021.

- **Mail:** Mail/courier to Janet M. de Jesus, MS, RD, HHS/OASH/ODPHP, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852. For written/paper submissions, ODPHP will post your comment, as well as any attachments, to www.regulations.gov.

Meeting materials for each meeting will be accessible at www.DietaryGuidelines.gov. Materials may be requested by email at diaryguidelines@hhs.gov.

Paul Reed,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2022–28510 Filed 12–30–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Mental Health.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(6), title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Mental Health, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Mental Health.

Date: February 2, 2023.

Time: 11:00 a.m. to 5:45 p.m.