including selecting an appropriate animal model; study monitoring; and study evaluation. The document also provides recommendations on test facility selection, animal housing, and records and reports, including animal study reports for premarket submissions. This guidance supersedes the final guidance ''General Considerations for Animal Studies for Cardiovascular Devices,'' issued on July 28, 2010.

A notice of availability of the draft guidance appeared in the **Federal Register** of October 14, 2015 (80 FR 61820). FDA considered comments received and revised the guidance as appropriate in response to the comments, including increased emphasis of the 3Rs to reduce, refine, and replace animal use in testing when feasible, reorganization of the guidance to better represent the study design, conduct, and reporting process, clarification of important terminology, and technical edits.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on general considerations for animal Studies intended to evaluate medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Persons unable to download an electronic copy of ''General Considerations for Animal Studies Intended to Evaluate Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00001802 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910–0119

Dated: March 21, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06254 Filed 3–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0853]

Yogurt Products Deviating From Standard of Identity; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have issued a temporary permit to Chobani, LLC (the applicant) to market test lower fat yogurt products deviating from the general definition and standard of identity for yogurt with modified milkfat and fat-containing flavoring ingredients, and yogurt deviating from the yogurt standard of identity by using ultrafiltered nonfat milk as a basic dairy ingredient. The temporary permit will allow the applicant to evaluate commercial viability of the products and to collect data on consumer acceptance of the products.

DATES: This temporary permit is effective for 15 months, beginning on the date the applicant introduces or causes introduction of the test products into interstate commerce, but not later than June 26, 2023.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: We are giving notice that we have issued a temporary permit to Chobani, LLC. We are issuing the temporary permit in accordance with 21 CFR 130.17, which addresses temporary permits for interstate shipments of experimental packs of food varying from the requirements of definitions and standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The temporary permit covers interstate market testing of the yogurt products. The test products deviate from the basic dairy ingredient provision of the yogurt standard of identity (21 CFR

131.200(b)). This temporary permit would allow the applicant to manufacture yogurts using ultrafiltered nonfat milk as a basic dairy ingredient through the addition of water and non-nutritive sweeteners. Consumers can distinguish this deviation in manufacturing from yogurts meeting the standard of identity for yogurt using the list of ingredients, wherein the ''ultrafiltered nonfat milk'' ingredient would be declared as such according to its common or usual name followed by a means to indicate to the consumer that the ingredient is not found in regular yogurt consistent with 21 CFR 130.10(g)(2).

The purpose of the temporary permit is to allow the applicant to market test the products throughout the United States. The temporary permit will allow the applicant to evaluate commercial viability of the products and to collect data on consumer acceptance of the products.

This temporary permit provides the temporary marketing of a maximum of 150,000,000 pounds (68,038,855.5 kilograms) of the test products. Chobani, LLC will manufacture the test products at its facilities located at 3450 Kimberly Rd. East, Twin Falls, ID 83301 and 669 County Rd. 25, New Berlin, NY 13411. Chobani, LLC will produce, market test, and distribute the test products throughout the United States.

Each ingredient used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This temporary permit is effective for 15 months, beginning on the date the applicant introduces or causes the introduction of the test products into interstate commerce, but not later than June 26, 2023.

Dated: March 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06390 Filed 3–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OWH Observance Champions; Correction

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Office of the Assistant Secretary for Health published a document in the **Federal Register** of September 14, 2022, inviting public and private sector organizations to apply to become a Women's Health Champion. The document includes contact information for a staff member who is no longer working in the Office on Women's Health.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of September 14, 2022, in FR Doc. 2022–19839, on page 56426, correct the For further information contact caption to read:

FOR FURTHER INFORMATION CONTACT: Gabriella Forte. Office on Women's Health, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services; 1101 Wootton Parkway, Rockville, MD 20852; Telephone: 202–690–7650. Email: *Womenshealth@hhs.gov.*

Dated: March 20, 2023.

Richelle Marshall,

Deputy Director for Operations and Management, Office of the Assistant Secretary for Health, Office on Women's Health.

[FR Doc. 2023–06319 Filed 3–27–23; 8:45 am]

BILLING CODE 4150–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Basic Cancer Immunology.

Date: April 27, 2023.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Virtual Assessments of Children and Caregivers.

Date: May 2, 2023.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jeanne M. McCaffery, Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3854, *jeanne.mccaffery@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 23, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–06404 Filed 3–27–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Cancer Etiology.

Date: April 11, 2023.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sarita Kandula Sastry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20782, 301–402–4788, *sarita.sastry@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.