Dated: March 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06374 Filed 3–27–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3419]

General Considerations for Animal Studies Intended To Evaluate Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''General Considerations for Animal Studies Intended to Evaluate Medical Devices.'' FDA developed this guidance document to assist medical device sponsors, testing facilities, and other persons involved in designing, conducting, and reporting the results of animal studies intended to assess the safety of medical devices to support premarket submissions. These animal studies typically provide initial evidence of device safety, which may include device performance and handling, and the biological effects when used in a living system.

DATES: The announcement of the guidance is published in the **Federal Register** on March 28, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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 public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *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 written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–3419 for ''General Considerations for Animal Studies Intended to Evaluate Medical Devices.'' Received comments 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 a comment with confidential information that you do not wish to be made publicly available, submit your comments 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 comments. 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 to read background documents or the electronic and written/paper comments received, 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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''General Considerations for Animal Studies Intended to Evaluate Medical Devices'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Judith A. Davis, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2220, Silver Spring, MD 20993–0002, 301–796–6636.

SUPPLEMENTARY INFORMATION:

I. Background

FDA developed this guidance document to assist medical device sponsors, testing facilities, and other persons involved in designing, conducting, and reporting the results of animal studies intended to support the safety of medical devices for premarket submissions. These animal studies typically provide initial evidence of device safety, which may include their performance and handling, and the biological effects when used in a living system. This guidance outlines general considerations for certain animal studies used to support device premarket submissions, when a suitable alternative to an animal study is not available. This guidance provides recommendations on study planning,

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.

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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