SUMMARY: The Food and Drug Administration (FDA or we) is announcing the revocation of the temporary permit issued to M.G. Waldbaum Co., a subsidiary of Michael Foods Egg Co., to market test ''ultrapasteurized liquid whole eggs'' and ''ultrapasteurized liquid whole eggs with citric acid'' because the need for the temporary permit no longer exists.

DATES: This permit is revoked as of January 2, 2025.

FOR FURTHER INFORMATION CONTACT: Marjan Morravej, Nutrition Center of Excellence, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Jessica Ritsick, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 21, 1989 (54 FR 30612), we issued a notice announcing that we had issued a temporary permit to Crystal Foods, Inc., 6465 Wayzata Blvd., Minneapolis, MN 55426, a subsidiary of Michael Foods, Inc., to market test experimental packs of ''ultrapasteurized liquid whole eggs'' and ''ultrapasteurized liquid whole eggs with citric acid,'' which we stated deviate from the standard of identity for liquid eggs at § 160.115 (21 CFR 160.115) because they were processed with increased heat treatment and aseptic processing and packaging. We refer to the temporary permit holder as ''the company'' throughout this notice. The temporary permit allowed the company to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility (Id.). In February 1991, FDA combined the original docket for the temporary permit (FDA–1989–P–0168) with other related dockets for the company into what is now docket number FDA–1991–P–0355.

After issuance of the temporary permit, the company requested, and FDA granted, several revisions:

- July 11, 1990 (55 FR 28456)—FDA amended the temporary permit to provide for package sizes larger than the designated 2.27 kilograms (5 pounds) to provide a broader base for data collection on consumer acceptance of the test products.
- September 20, 1990 (55 FR 38753)—FDA extended the temporary permit so the company could continue experimental market testing of the products and continue gathering data in support of its petition to amend the standard of identity for liquid eggs at § 160.115. As part of the extension, FDA invited interested persons to participate in the market test under the conditions in the temporary permit, except for the designated area of distribution. We have no records that show that any interested persons notified us of their intent to participate in the market test, as required under § 130.17(i) (21 CFR 130.17(i)).
- March 22, 1991 (56 FR 12206)—FDA amended the temporary permit to allow the test products to be packaged in aseptic packages ranging in size from 42.5 grams (1.5 ounces) to 1 kilogram (2.2 pounds). Additionally, as requested by the company, we changed the name and address of the permit holder from Crystal Foods, Inc., Minneapolis, MN 55426, to M.G. Waldbaum Co., Wakefield, NE 68784.

In the time since the temporary permit was originally issued, FDA has concluded that the temporary permit is not necessary, because the standard of identity in § 160.115 provides for the treatment process used by the company under the temporary permit. Our regulation, at § 160.115(a), states that liquid eggs must be pasteurized or otherwise treated to destroy all viable *Salmonella* microorganisms. The specific process used by the company under the temporary permit—increased heat treatment and aseptic processing and packaging—is consistent with § 160.115(a). Specifically, the standard of identity for liquid eggs permits other treatments that destroy all viable *Salmonella* microorganisms. As such, we have concluded that the temporary permit is not necessary to market liquid eggs using the company's process, consistent with the standard of identity.

In addition, in April 2024, FDA contacted the company via email regarding the current use of its temporary permit. The company did not object to FDA revoking the temporary permit under § 130.17(g)(3).

Therefore, under § 130.17(g)(3), we are revoking the company's temporary permit because the need for it no longer exists.

Dated: December 20, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31470 Filed 12–31–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4974]

Advanced Manufacturing Technologies Designation Program; Guidance for Industry; 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 for industry entitled ''Advanced Manufacturing Technologies Designation Program.'' FDA encourages the early adoption of advanced manufacturing technologies (AMTs) by the pharmaceutical industry, which can improve the reliability and robustness of the manufacturing process and can benefit patients by enhancing product quality and reducing drug development time or increasing or maintaining the supply of drugs that are life-supporting, life-sustaining, of critical importance to providing health care, or in shortage. This guidance provides recommendations to persons and organizations interested in participating in FDA's Advanced Manufacturing Technologies Designation Program, which facilitates the development of drugs manufactured using an AMT that has been designated as such under the program. The guidance finalizes the draft guidance of the same title issued on December 13, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on January 2, 2025.

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–2023–D–4974 for ''Advanced Manufacturing Technologies Designation Program.'' 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)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993, 240–402–4652; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Advanced Manufacturing Technologies Designation Program.'' FDA's Advanced Manufacturing Technologies Designation Program, which is required under section 506L of the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. 356l), offers a framework for persons or organizations (*e.g.,* applicants, contract manufacturers, technology developers) to request designation of a method or combination of methods of manufacturing a drug as an AMT. The program facilitates the development of drugs as described in section 506L(b) of the FD&C Act that are manufactured using a designated AMT, submitted in an application under section 505 of the FD&C Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262), and regulated by CDER or CBER. An application or supplemental application referencing a designated AMT can receive certain benefits under the program, such as FDA's early interaction with applicants regarding the development and manufacture of drugs using a designated AMT, as described in section 506L(c)(1) of the FD&C Act.

The guidance outlines the eligibility criteria for AMT designation, the submission and assessment process for requests, including data and information to be submitted, and the benefits of receiving an AMT designation, among other information, and includes a questions and answers section to cover additional details about key concepts important for program utilization. The guidance finalizes the draft guidance of the same title issued on December 13, 2023 (88 FR 86333). FDA considered comments received on the draft guidance in finalizing the guidance. FDA made changes from the draft guidance to improve clarity about the AMT designation process, the content of AMT designation requests, the roles and responsibilities of different entities involved in the development and use of designated AMTs, and the relationship between the Advanced Manufacturing Technologies Designation Program and other FDA programs addressing emerging or advanced technologies.

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 ''Advanced Manufacturing Technologies Designation Program.'' 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. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. FDA is issuing this guidance, as final, in accordance with section 506L of the FD&C Act, which directs FDA to initiate a program and establish a process for

AMT designation, including information collection provisions subject to review and approval by OMB under the PRA. Section 506L(e)(2) of the FD&C Act further directs FDA to issue program guidance. Before implementing the information collection provisions of the guidance, FDA will publish a notice in the **Federal Register** continuing to invite public comment on the proposed collections of information (see 88 FR 86333) and announce OMB's decision to approve, modify, or disapprove the collections of information, including the OMB control number(s).

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov*.

Dated: December 27, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31493 Filed 12–31–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 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: National Institute on Aging Initial Review Group; Career Development for Established Investigators and Conference Grants Study Section.

Date: February 13–14, 2025.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, 301–496–6477, *rajasri.roy@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 26, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–31444 Filed 12–31–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 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: National Institute on Aging Initial Review Group; Career Development for Clinicians/Health Professionals Study Section.

Date: February 10–11, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute on Aging, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Mariel Jais, Ph.D., M.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 5601 Fishers Lane, Suite 8B, Rockville, MD 20892, (301) 594–2614, *mariel.jais@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 26, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–31441 Filed 12–31–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 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: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Nutrition Obesity Research Centers (P30–P2C).

Date: March 12–13, 2025.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015.

Meeting Format: In Person and Virtual Meeting.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institutes of Health, 6707 Democracy Boulevard, Rm. 7021, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 26, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–31445 Filed 12–31–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as