4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1991-P-0355]

Liquid Eggs Deviating From the Standard of Identity; Revocation of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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.

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