

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–1103 for “Sec. 555.250 Major Food Allergen Labeling and Cross-contact.” 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.” We will review this copy, including the claimed confidential information, in our 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 the draft guidance to Office of Compliance (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

Yinqing Ma, Office of Compliance (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2479, email: Yinqing.ma@fda.hhs.gov; or Denise See, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft Compliance Policy Guide (CPG) entitled “Sec. 555.250 Major Food Allergen Labeling and Cross-contact.” This draft CPG would update and replace existing guidance for FDA staff on FDA’s enforcement policy regarding major food allergen labeling and cross-contact. The content of current CPG Sec. 555.250 was written before the enactment of three major laws that are the foundation of FDA’s regulatory framework for major food allergens: Food Allergen Labeling and Consumer Protection Act (2004), FDA Food Safety Modernization Act (2011), and the Food Allergy Safety, Treatment, Education and Research Act (2021). The current CPG Sec. 555.250 also does not reflect requirements in our regulation entitled “Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food” (now codified at 21 CFR part 117).

We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of

information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/FoodGuidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: May 12, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10523 Filed 5–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2226]

Cheese Products Deviating From Identity Standard; 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 extension of a temporary permit issued to Bongards Creameries (the applicant) to market test several pasteurized standardized cheeses that deviate from the U.S. standards of identity for cheese products. The extension allows the applicant to continue to evaluate commercial viability of the products and to collect data on consumer acceptance of the products, in support of a petition to amend the standard of identity for cheese products. We also invite other interested parties to participate in the market test.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity of cheese products that may result from the petition or 30 days after denial of the petition.

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: In accordance with § 130.17 (21 CFR

130.17), we issued a temporary permit to Bongards Creameries, 250 Lake Drive East, Chanhassen, MN 55317, to market test products that deviate from the standards of identity for cheese products under §§ 133.167, 133.169, 133.170, and 133.173 (21 CFR 133.167, 133.169, 133.170, and 133.173) (85 FR 80118, December 11, 2020). We issued the permit to facilitate market testing of products that deviate from the requirements of the standard of identity for cheese products issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate marketing tests of cheese products.

The test products deviate from the standards of identity for cheese products under §§ 133.167, 133.169, 133.170, and 133.173. For the purpose of this permit, natamycin, which is not permitted under the standards of identity for these cheese products, would be added as a mold inhibitor in the standardized cheeses. The inhibitor would be incorporated into blended and processed cheese just prior to pasteurization and further cast into slices (or packaging into loaves or other final forms as in the case of pasteurized process cheese spread). Natamycin, which is stable under typical thermal processing conditions for pasteurized cheeses, would be added directly to cheese blends just prior to pasteurization, as is done with other mold inhibitors such as sorbic acid, sodium propionate, and their approved variants. The final concentration of natamycin would not exceed 20 parts per million and would be effective at producing process and blended slices with a shelf life of up to 150 days before seeing mold growth.

The test products meet all the requirements of the standard with the exception of this deviation.

On December 22, 2022, the applicant asked us to extend the temporary permit so the applicant could have more time to market test the cheese products and gain additional consumer acceptance in support of the petition to amend the standard for cheese products. We find that it is in the interest of consumers to extend the permit for continued market testing of the cheese products to gain additional information on consumer expectations and acceptance. Therefore, under § 130.17(i), we are extending the temporary permit granted to Bongards Creameries for temporary marketing of a maximum of 100 million pounds (45,359,237 kilograms) of cheese products to provide continued market testing of the specified amount of product for the applicant on an annual basis. The new expiration date of the

permit will be either the effective date of a final rule amending the standard of identity for cheese products that may result from the petition or 30 days after denial of the petition. All other conditions and terms of this permit remain the same.

In addition, we invite interested persons to participate in the market test under the conditions of the permit, except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Branch Chief, Product Evaluation Labeling Branch, Division of Food Labeling and Standards, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, via FDAAfoodsProgramTMP@fda.hhs.gov. The notification must describe the test products and the area of distribution, specify and justify the amount requested, and include the labeling that will be used for the test product (*i.e.*, a draft label for each size of container and each brand of product to be market tested) (see § 130.17(c)). The information panels on the labels of the test products must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by 21 CFR part 101.

Dated: May 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–10438 Filed 5–16–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before July 17, 2023.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 264–0041 and PRA@HHS.GOV.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–60D

and project title for reference, to Sherrette A. Funn, email: Sherrette.Funn@hhs.gov, PRA@HHS.GOV or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Critical Infrastructure Protection Healthcare and Public Health (HPH) Partnership Data Collection.

Type of Collection: NEW.

OMB No.: 0990–new.

Abstract: The Administration for Strategic Preparedness and Response's (ASPR) Office of Critical Infrastructure Protection (CIP) serves as the (HPH) Sector Risk Management Agency (SRMA) designee on behalf of the Department of Health and Human Services (HHS) as codified by the 2021 National Defense Authorization Act (NDAA), supporting the HPH Sector to prepare for future threats, manage risks, coordinate effective response, and recover from human-caused and naturally occurring threats and hazards.

CIP promotes resilience of the nation's health critical infrastructure by working directly with public and private sector partners to establish risk assessment tools, foster information sharing, provide technical resources and assistance, and lead programs to prepare for, respond to, and recover from human-caused and naturally occurring threats and hazards. CIP specifically manages the (HPH) Sector Critical Infrastructure Protection Partnership (HPH Partnership), a coordinating body of more than 300 private sector organizations and federal and state, tribal, local, and territorial (STLT) government entities. CIP relies on a strong partnership federal and STLT government entities through the Government Coordinating Council (GCC) and with critical infrastructure owners and operators through the private Sector Coordinating Council (SCC). Together, the councils of the HPH Partnership form a private-public network that promotes situational awareness, coordination, capacity-