DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3787]

Electromagnetic Compatibility of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of November 17, 2020. In the notice of availability, FDA requested comments on the draft guidance for industry and FDA staff entitled ''Electromagnetic Compatibility of Medical Devices.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published on November 17, 2020 (85 FR 73276). Submit either electronic or written comments on the draft guidance by February 16, 2021, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–3787 for ''Electromagnetic Compatibility (EMC) of 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 draft guidance document entitled ''Electromagnetic Compatibility (EMC) of 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, 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 request.

FOR FURTHER INFORMATION CONTACT: Seth J. Seidman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1108, Silver Spring, MD 20993–0002, 301–796–2477; or Stephen Ripley, 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

In the **Federal Register** of November 17, 2020, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled ''Electromagnetic Compatibility of Medical Devices.''

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the

notice of availability for 30 days, until February 16, 2021. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the electromagnetic compatibility of 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 draft 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* or from the Center for Biologics Evaluation and Research at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* This guidance document is also available at *https://www.regulations.gov* and at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Electromagnetic Compatibility (EMC) of Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please include the complete title and the document number 16040 to identify the guidance you are requesting.

Dated: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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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 that a temporary permit has been 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 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 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 March 11, 2021.

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 Bongards Creameries. 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 standards of identity issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

The permit covers interstate marketing test of several pasteurized standardized cheeses. The test products deviate from the standards of identity for cheese products under 21 CFR 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 purpose of the temporary permit is to allow the applicant to market test the products throughout the United States. The permit will allow the applicant to evaluate commercial viability of the products and to collect data on consumer acceptance of the products.

This permit provides for the temporary marketing of a maximum of 100 million pounds (45,359,237 kg) of the test products. The test products will be manufactured at the Bongards Creamery facilities located at 13200 County Rd. 51, Bongards, MN 55368, and 3001 Hwy. 45 Bypass West, Humboldt, TN 38343.

Bongards Creameries will produce, market test, and distribute the test products throughout the United States. The following sliced cheese products will be market tested: American Pasteurized Process Cheese, Reduced Fat and Reduced Sodium American Pasteurized Process Cheese, Restricted Melt American Pasteurized Process Cheese, American Swiss Pasteurized Process Cheese, White American Pasteurized Process Cheese, American with Jalapeno Pasteurized Process Cheese, Pasteurized Blended Cheddar Cheese, Pasteurized Reduced Fat Cheddar Cheese, Pasteurized Blended Swiss Cheese, Pasteurized Blended Pepper Jack Cheese, Pasteurized Blended Low-Moisture Part Skim Mozzarella Cheese, and Pasteurized Blended Provolone Cheese.

In addition, the following products will be market tested for further manufacturing: Yellow Restricted Melt Process American Slice, Yellow Reduced Fat/Reduced Sodium Process American Slice, Yellow Reduced Sodium Process American Slice, and Yellow Process American Cheese Food Slice.

Each ingredient used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101. This permit is effective for 15 months, beginning on the date the applicant introduces or causes the introduction of the test products into