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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the electromagnetic compatibility of medical devices.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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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.

[FR Doc. 2020–27350 Filed 12–10–20; 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 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

interstate commerce, but not later than March 11, 2021.

Dated: December 7, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27197 Filed 12–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2197]

VistaPharm, Inc., et al.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 11, 2021.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040323	Prednisolone Syrup, 15 milligrams (mg)/5 milliliters (mL)	VistaPharm, Inc., 7265 Ulmerton Rd., Largo, FL 33771
ANDA 075782	Valproic Acid Syrup, 250 mg/5 mL	Do.
ANDA 076188	Fosinopril Sodium Tablets, 10 mg, 20 mg, and 40 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 076189	Mirtazapine Tablets, 15 mg, 30 mg, and 45 mg	Do.
ANDA 077537	Glyburide Tablets, 1.25 mg, 2.5 mg, and 5 mg	Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 077672	Stavudine Capsules, 15 mg, 20 mg, 30 mg, and 40 mg	Do.
ANDA 085055	Tylenol W/Codeine No. 1 (acetaminophen and codeine phosphate) Tablets, 300 mg; 7.5 mg. Tylenol W/Codeine No. 2 (acetaminophen and codeine phosphate) Tablets, 300 mg; 15 mg. Tylenol W/Codeine No. 3 (acetaminophen and codeine phosphate) Tablets, 300 mg; 30 mg. Tylenol W/Codeine No. 4 (acetaminophen and codeine phosphate) Tablets, 300 mg; 60 mg.	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, P.O. Box 300, Raritan NJ 08869
ANDA 087266	Lindane Shampoo, 1%	Olta Pharmaceuticals Corp. (an Akorn Company), 1925 West Field Ct., Suite 300, Lake Forest, IL 60045
ANDA 087313	Lindane Lotion, 1%	Do.
ANDA 089003	Phenytoin Sodium Injection, 50 mg/mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of January 11, 2021. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on January 11, 2021 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27303 Filed 12–10–20; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0529]

Qualification Process for Drug Development Tools; Guidance for Industry; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Qualification Process