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Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 11, 2021.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