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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of January 11, 2021.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

for Drug Development Tools; Guidance for Industry; Availability'' that appeared in the **Federal Register** of November 25, 2020. The document announced the availability of a final guidance for industry and FDA staff that met the 21st Century Cures Act's requirement to issue guidance on this qualification process and elaborated on the new qualification process and transparency requirements and discusses the taxonomy for biomarkers and other drug development tools. The document was published with incorrect information in the Paperwork Reduction Act of 1995 section. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Chris Leptak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6461, Silver Spring, MD 20993–0002, 301–796–0017; or Stephen Ripley, Center for Biologics Evaluation and Research, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002; 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 2020 (85 FR 75334), in FR Doc. 2020–26051, the following correction is made:

On page 75336, in the first column, under the heading, ''II. Paperwork Reduction Act of 1995'', the paragraph is corrected to read:

''While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to submissions of investigational new drug applications have been approved under OMB control number 0910–0014; the collections of information pertaining to submissions of new drug applications and abbreviated new drug applications have been approved under OMB control number 0910–0001; and the collections of information pertaining to submissions of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910–0338.''

Dated: December 8, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27288 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–D–0064]

Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe Notices; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, we, or Agency) is announcing the availability of a final guidance for industry #262 entitled ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices.'' The guidance provides uniform, consistent process information to industry to facilitate effective and efficient review of pre-consultation submissions for animal food additives or GRAS notices for intended use in animal food.

DATES: The announcement of the guidance is published in the **Federal Register** on December 11, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–0064 for ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices.'' 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