Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. 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 September 7, 2018 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: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16985 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2702]

Merck Sharp & Dohme Corporation, et al.; Withdrawal of Approval of Four New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications 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
NDA 005619	Aminohippurate Sodium (PAH) 20% sterile solution Injection, 2 grams in 10 milliliter (mL) vials.	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 008506	Hydrocortone (hydrocortisone) Tablets USP, 10 milligrams (mg) and 20 mg.	Do.
NDA 011891	Durabolin (nandrolone phenpropionate) Injection, 25 mg/mL and 50 mg/mL.	Organon USA, Inc., Subsidiary of Merck & Company, Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020301	Ortho-Cept (desogestrel and ethinyl estradiol) Tablets USP, 0.15 mg/0.03 mg (21-Day and 28-Day Regimens).	Janssen Pharmaceuticals, Inc., 920 U.S. Hwy. 202, P.O. Box 300, Raritan, NJ 08869–0602.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. 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 September 7, 2018 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: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16982 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1692]

Elemental Impurities in Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Elemental Impurities in Drug Products.'' This guidance finalizes the draft guidance issued July 1, 2016, which provides recommendations regarding the control of elemental impurities of human drug products marketed in the United States consistent with the implementation of International Council for Harmonisation (ICH) guidance for industry entitled ''Q3D Elemental Impurities'' (ICH Q3D). This guidance will also assist manufacturers of compendial drug products in responding to the issuance of the United States Pharmacopeia (USP) requirement for the control of elemental impurities.

DATES: The announcement of the guidance is published in the **Federal Register** on August 8, 2018.

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