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.

FOR FURTHER INFORMATION CONTACT: Robert Berlin, Center for Drug Evaluation and Research, Office of New Drugs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6373, Silver Spring, MD, 20993, 301–796–8828; Irene Chan, Center for Drug Evaluation and Research, Office of New Drugs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD, 20993, 301–796–3962; 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; Andrew Yeatts, Center for Devices and Radiological Health, Food and Drug Administration 10903 New Hampshire Ave., Bldg. 66, Rm. 5452, Silver Spring, MD 20993–0002, 301–796–4539; or Patricia Love, Office of Special Medical Programs, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5144, Silver Spring, MD 20993–0002, 301–796–8933.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2019, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry entitled ''Bridging for Drug-Device and Biologic-Device Combination Products.''

The Agency has received requests for an extension of the comment period for the notice of availability. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the notice of availability. FDA has considered the requests and is extending the comment period for the notice of availability for 60 days, until April 20, 2020. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without compromising the timely publication of the final version of the guidance.

Dated: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03023 Filed 2–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5608]

Wockhardt Limited, et al.; Withdrawal of Approval of 28 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 28 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 March 16, 2020.

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 040732 ..	Phenytoin Sodium Capsules, 100 milligrams (mg) (Extended)	Wockhardt Limited, c/o Morton Grove Pharmaceuticals, Inc., 6451 Main St., Morton Grove, IL 60053.
ANDA 065230 ..	Ceftriaxone for Injection, Equivalent to (EQ) 250 mg base/vial; EQ 500 mg base/vial; EQ 1 gram (g) base/vial; EQ 2 g base/vial.	Hospira, Inc., 275 North Field Dr., Bldg. H1, Lake Forest, IL 60045.
ANDA 065231 ..	Ceftriaxone for Injection, EQ 1 g base/vial; EQ 2 g base/vial Piggy Back.	Do.
ANDA 065290 ..	Cefotaxime Sodium for Injection, EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 065292 ..	Cefotaxime Sodium for Injection, EQ 10 g base/vial Pharmacy Bulk Package.	Do.
ANDA 065293 ..	Cefotaxime Sodium for Injection, EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 065312 ..	Cefoxitin for Injection, EQ 10 g base/vial Pharmacy Bulk Package.	Do.
ANDA 065313 ..	Cefoxitin for Injection, EQ 1 g base/vial; EQ 2 g base/vial	Do.
ANDA 065369 ..	Cefepime Hydrochloride (HCl) for Injection, EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 065483 ..	Cefuroxime Sodium for Injection, EQ 750 mg base/vial; EQ 1.5 g base/vial.	Do.

Application No.	Drug	Applicant
ANDA 065484 ..	Cefuroxime Sodium for Injection, EQ 7.5 g base/vial Pharmacy Bulk Package.	Do.
ANDA 065503 ..	Cefuroxime Sodium for Injection, EQ 1.5 g base/vial	Do.
ANDA 075250 ..	Prednisolone Sodium Phosphate Oral Solution, EQ 15 mg base/5 milliliters (mL).	Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 075618 ..	Acetaminophen, Butalbital, Caffeine, and Codeine Phosphate Capsules, 325 mg, 50 mg, 40 mg, and 30 mg.	Hikma Pharmaceuticals USA Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 090375 ..	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial.	Hospira, Inc.
ANDA 090646 ..	Ampicillin and Sulbactam for Injection, EQ 10 g base/vial and EQ 5 g base/vial.	Do.
ANDA 090653 ..	Ampicillin and Sulbactam for Injection, EQ 1 g base/vial and EQ 500 mg base/vial; EQ 2 g base/vial and EQ 1 g base/vial.	Do.
ANDA 090825 ..	Imipenem and Cilastatin for Injection, EQ 250 mg base/vial and 250 mg base/vial; EQ 500 mg base/vial and 500 mg/vial.	Do.
ANDA 090940 ..	Meropenem for Injection, 500 mg/vial, and 1 g/vial	Do.
ANDA 091007 ..	Imipenem and Cilastatin for Injection, EQ 500 mg base/vial and 500 mg/vial.	Do.
ANDA 202268 ..	Cefepime HCl for Injection, EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 202563 ..	Ceftriaxone for Injection, EQ 1 g base/vial; EQ 2 g base/vial ..	Do.
ANDA 202864 ..	Ampicillin Sodium for Injection, EQ 250 mg base/vial; EQ 500 mg base/vial; EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 202865 ..	Ampicillin Sodium for Injection, EQ 10 g base/vial Pharmacy Bulk Package.	Do.
ANDA 203132 ..	Cefotaxime Sodium for Injection, EQ 1 g base/vial; EQ 2 g base/vial.	Do.
ANDA 204879 ..	Pyridoxine HCl Injection, 100 mg/mL	Mylan Institutional, LLC, 4901 Hiawatha Dr., Rockford, IL 61103.
ANDA 206062 ..	Doxorubicin HCl for Injection, USP, 20 mg/vial	Hisun Pharmaceutical Hangzhou Co., LTD, 200 Crossing Blvd., 2nd Floor, Bridgewater, NJ 08807.
ANDA 206195 ..	Daunorubicin HCl for Injection, EQ 20 mg base/vial	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of March 16, 2020. Approval of each entire application is withdrawn, including any strengths or products 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 March 16, 2020 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: February 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03025 Filed 2–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1398]

Mitigation Strategies To Protect Food Against Intentional Adulteration; Draft 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 supplemental draft guidance for industry entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration: Guidance for Industry.'' This supplemental draft guidance document, when finalized, will help food facilities that manufacture, process, pack, or hold food, and that are required to register under the Federal Food, Drug, and Cosmetic Act (FD&C Act) comply with the requirements of our regulation entitled ''Mitigation Strategies to Protect Food Against Intentional Adulteration.''

DATES: Submit either electronic or written comments on the draft guidance by June 15, 2020 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.*