transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. The Centers for Medicare and Medicaid Services (CMS) will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on performance.gov to help build transparency and accountability of Federal programs to the customers they serve.

CMS will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. CMS may also utilize observational techniques to collect this information.

*Form Number:* CMS–10710 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; Private Sector (business or other for-profits, not-for-profit institutions), State, Local or Tribal governments; Federal government; and Universities; *Number of Respondents:* 1,001,750; *Number of Responses:* Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 2 hours to participate in an interview; *Total Annual Hours:* 51,175. (For questions regarding this collection contact Aaron Lartey at 410–786–7866).

Dated: February 11, 2020.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2020–03046 Filed 2–13–20; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–D–5585]**

### Bridging for Drug-Device and Biologic-Device Combination Products; Draft Guidance for Industry; Availability; Extension of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability, extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of December 19, 2019. In the notice of availability, FDA requested comments on the draft guidance for industry entitled ''Bridging for Drug-Device and Biologic-Device Combination Products.'' The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice of availability published December 19, 2019 (84 FR 69749). Submit either electronic or written comments by April 20, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 20, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 20, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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–2019–D–5585 for ''Bridging for Drug-Device and Biologic-Device Combination Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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 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. |