solution is a mood-stabilizing agent indicated as monotherapy for the following treatment of bipolar I disorder: treatment of acute manic and mixed episodes in patients 7 years and older; and maintenance treatment in patients 7 years and older.

Lithium citrate oral solution, 8 mEq/5 mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Saptalis Pharmaceuticals, LLC submitted a citizen petition dated November 2, 2022 (Docket No. FDA–2022–P–2752), under § 10.30 (21 CFR 10.30), requesting that the Agency determine whether lithium citrate oral solution, 8 mEq/5 mL, was withdrawn from sale for reasons of safety or effectiveness. Hyman, Phelps & McNamara, P.C. separately submitted a citizen petition dated December 6, 2022 (Docket No. FDA–2022–P–3125), under § 10.30, requesting that the Agency make the same determination.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that lithium citrate oral solution, 8 mEq/5 mL, was not withdrawn for reasons of safety or effectiveness. The Petitioners have identified no data or other information suggesting that lithium citrate oral solution, 8 mEq/5 mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of lithium citrate oral solution, 8 mEq/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list lithium citrate oral solution, 8 mEq/5 mL, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04560 Filed 3–6–23; 8:45 am]

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300 mg Carbonate/5mL.'' The currently approved labeling refers to this drug product as ''Lithium Oral Solution USP, 8 mEq per 5 mL'' and provides that the dosage strength for Lithium Oral Solution in terms of lithium content, 8 mEq/5mL, is equivalent to 300 mg lithium carbonate/5 mL. For purposes of this determination, we use the current label's description, ''Lithium Oral Solution USP, 8 mEq per 5 mL.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1998–D–0038]

Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern; Revised 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 announcing the availability of a draft guidance for industry that appeared in the **Federal Register** of December 19, 2022. In that notice, FDA requested comments on draft guidance for industry (GFI) #152 entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published December 19, 2022 (87 FR 77619). Submit either electronic or written comments by May 19, 2023, 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.*
- 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–1998–D–0038 for ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' 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 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ruby Singh, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0794, *ruby.singh@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 19, 2022, FDA published a notice announcing the availability of a draft guidance for industry entitled ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern,'' and requesting comments on the proposed GFI.

Interested persons were originally given until March 20, 2023, to comment on the document. The Agency has received a request for an extension of the comment period. The request stated that an additional 90 days would allow interested parties to thoroughly consider the request for input. FDA has considered the request and is extending the comment period for the request for comments for 60 days, until May 19, 2023. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments.

Dated: March 1, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04562 Filed 3–6–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4853]

Receipt of Notice That a Patent Infringement Complaint Was Filed Against a Biosimilar or Interchangeable Biosimilar Applicant

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing notice that an applicant for a biologics license application (BLA) for a biosimilar or interchangeable biosimilar product submitted under the Public Health Service Act (PHS Act) (a ''subsection (k) applicant'') notified FDA that an action for patent infringement was filed in connection with the applicant's BLA. Under the PHS Act, within 30 days after the subsection (k) applicant is served with a complaint in an action for patent infringement described under the PHS Act, the subsection (k) applicant shall provide the Secretary of HHS with notice and copy of such complaint. FDA is required to publish notice of the complaint in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993–0002, 301–796–1042, *Sandra.Benton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111–148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)) sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product.

Section 351(l) of the PHS Act describes certain procedures for exchanging patent information and resolving patent disputes between a subsection (k) applicant and the holder of the BLA reference product. If a subsection (k) applicant is served with a complaint in an action for a patent infringement described in section 351(l)(6) of the PHS Act, the subsection (k) applicant is required to provide the Secretary of HHS with notice and a copy of the complaint within 30 days of service. FDA is required to publish notice of a complaint received under section 351(l)(6)(C) of the PHS Act in the **Federal Register**.

FDA received notice of the following complaint under section 351(l)(6)(C) of the PHS Act: *Regeneron Pharmaceuticals, Inc.* v. *Mylan Pharmaceuticals Inc.,* 1:22–CV–61 (N.D.W. Va., filed August 2, 2022).

FDA has only a ministerial role that is limited to publishing notice of a complaint received under section 351(l)(6)(C) of the PHS Act and does not perform a substantive review of the complaint.

Dated: February 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–04583 Filed 3–6–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0680]

Fosun Pharma USA Inc.; Withdrawal of Approval of Abbreviated New Drug Application for Pemoline Tablets, 18.75 Milligrams, 37.5 Milligrams, and 75 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 075286 for pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Fosun Pharma USA Inc. (Fosun), 104 Carnegie Center, Princeton, NJ 08540. Fosun requested that approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of March 7, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire