

appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

#### SUPPLEMENTARY INFORMATION:

**Agenda:** The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On April 20, 2023, the committee will discuss, make recommendations, and vote on clinical information related to the De Novo request for the NUsurface Meniscus Implant sponsored by Active Implants, Inc. The device is a polymeric disc-shaped device implanted in the medial compartment of the knee to distribute load between the distal femur and proximal tibia and is intended to improve pain and function in the medial compartment of a knee in which the medial meniscus has been resected.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material and the link to the online teleconference meeting room will be available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down and select the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 4, 2023. Oral presentations from the public will be scheduled on April 20, 2023, between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 27, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably

accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 28, 2023.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto:fdaoma@fda.hhs.gov) or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett at [Artair.Mallett@fda.hhs.gov](mailto:Artair.Mallett@fda.hhs.gov) or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-04561 Filed 3-6-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA-2022-P-2752 and FDA-2022-P-3125]**

#### **Determination That Lithium Citrate Oral Solution, 8 Milliequivalents/5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that lithium citrate oral solution, 8 milliequivalents (mEq)/5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet

relevant legal and regulatory requirements.

#### **FOR FURTHER INFORMATION CONTACT:**

Caitlin Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6240, Silver Spring, MD 20993-0002, 240-402-4318, [Caitlin.Callahan@fda.hhs.gov](mailto:Caitlin.Callahan@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Lithium citrate oral solution, 8 mEq/5 mL, is the subject of NDA 018421, held by Hikma Pharmaceuticals USA Inc., and initially approved on December 23, 1980.<sup>1</sup> Lithium citrate oral

<sup>1</sup> In their citizen petitions, petitioners Saptalis Pharmaceuticals LLC, and Hyman, Phelps & McNamara, P.C., refer to this drug product, respectively, as "Lithium Citrate Syrup EQ 300 mg Carbonate/5mL" and "Lithium Citrate Oral Syrup,"

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

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.”

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]

**BILLING CODE 4164–01–P**

## 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