enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION:**

*Agenda:* On September 10, 2019, the Committee will discuss and make recommendations on the topic ''Cybersecurity in Medical Devices: Communication That Empowers Patients.'' Medical devices are increasingly connected to the internet, hospital networks, and other medical devices to provide features that improve healthcare and increase the ability of healthcare providers to treat patients. These same features may also increase cybersecurity risks. Preserving the benefit of these devices requires continuous vigilance as well as timely and effective communication to medical device users about evolving cybersecurity risks. The recommendations provided by the committee will address which factors should be considered by FDA and industry when communicating cybersecurity risks to patients and to the public, including but not limited to the content, phrasing, the methods used to disseminate the message and the timing of that communication. The recommendations will also address concerns patients have about changes to their devices to reduce cybersecurity risks as well as the role of other stakeholders such as healthcare providers in communicating cybersecurity risks to patients. Additional information about cybersecurity can be found at *https://www.fda.gov/medical-devices/digital-health/cybersecurity*.

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee.* Select the link for the 2019 Meeting Materials.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled between approximately 10:45 a.m. to 12:15 p.m. on September 10, 2019. Those individuals interested in making formal oral presentations should notify the contact person and submit 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 July 22, 2019. 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 July 24, 2019. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the Committee may send written submissions to the contact person on or before July 30, 2019.

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,* or 301–796–9638 at least 7 days in advance of the meeting.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings. Please be advised that, for the roundtable portion of the meeting, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

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

Dated: June 27, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–14141 Filed 7–2–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–2040]**

### Liebel-Flarsheim Company LLC, et al.; Withdrawal of Approval of 11 New Drug Applications

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 11 new drug applications (NDAs) 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 August 2, 2019.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

**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 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 016983 | Conray 30 (iothalamate meglumine) Injection, 30% | Liebel-Flarsheim Co. LLC, 1034 South Brentwood Blvd., Suite 800, Richmond Heights, MO 63117. |
| NDA 018972 | Cordarone (amiodarone HCl) Tablets, 200 mg | Wyeth Pharmaceuticals LLC, P.O. Box 8299, Philadelphia, PA 19101–8299. |
| NDA 019009 | Maxair Inhaler (pirbuterol acetate inhalation aerosol), equivalent to (EQ) 0.2 mg base/inhalation. | Bausch Health US, LLC, 400 Somerset Corporate Blvd., Bridgewater, NH 08807. |

| Application No. | Drug | Applicant |
|---|---|---|
| NDA 019292 | MD–76R (diatrizoate meglumine and diatrizoate sodium) Injection, 66%/10%. | Liebel-Flarsheim Co. LLC. |
| NDA 020014 | Maxair Autohaler (pirbuterol acetate inhalation aerosol), EQ 0.2 mg base/inhalation. | Bausch Health US, LLC. |
| NDA 021041 | DepoCyt (cytarabine liposome) Injection, 10 mg/mL | Pacira Pharmaceuticals, Inc., 5 Sylvan Way, Suite 300, Parsippany, NJ 07054. |
| NDA 021338 | Ionsys (fentanyl iontophoresis transdermal system), 40 mcg/activation. | The Medicines Co., 8 Sylvan Way, Parsippany, NJ 07054. |
| NDA 021575 | Fosamax (alendronate sodium) Oral Solution, EQ 70 mg base/75 mL. | Merck Sharp & Dohme Corp., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889–0100. |
| NDA 022222 | Ultresa (pancrelipase (amylase, lipase, protease)), Delayed-Release Capsules, 8,000 USP Units/4,000 USP Units/8,000 USP Units and 27,600 USP Units/13,800 USP Units/27,600 USP Units, and 41,400 USP Units/20,700 USP Units/41,400 USP Units, and 46,000 USP Units/23,000 USP Units/46,000 USP Units. | Allergan Sales, LLC, 5 Giralda Farms, Madison, NJ 07940. |
| NDA 022396 | Dyloject (diclofenac sodium) Injection, 37.5 mg/mL | Javelin Pharmaceuticals, Inc., a subsidiary of Hospira Inc., 275 North Field Dr., Dept. 0392, Bldg. H1–3S, Lake Forest, IL 60045. |
| NDA 203568 | Kynamro (mipomersen sodium) Injection, 200 mg/mL | Kastle Therapeutics, 181 West Madison St., Suite 300, Chicago, IL 60602. |

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of August 2, 2019. 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 August 2, 2019 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: June 28, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–14219 Filed 7–2–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–P–1366]**

### Determination That CLAFORAN (Cefotaxime Sodium) for Injection, 500 Milligrams/Vial, 1 Gram/Vial, 2 Grams/Vial and 10 Grams/Vial, 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 CLAFORAN (cefotaxime sodium) for injection, 500 milligrams (mg)/vial, 1 gram (g)/vial, 2 g/vial and 10 g/vial, 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:** Beth Holck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 240–402–7133.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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.

CLAFORAN (cefotaxime sodium) for injection, 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial, is the subject of NDA 050547, held by US Pharmaceutical Holdings II LLC, and initially approved on March 11, 1981. CLAFORAN is indicated for the treatment of patients with serious bacterial infections in eight different organ systems caused by susceptible strains of microorganisms, as specified in the labeling.

In a letter dated February 9, 2018, US Pharmaceutical Holdings II LLC notified FDA that CLAFORAN (cefotaxime for injection) 500 mg/vial, 1 g/vial, 2 g/vial and 10 g/vial was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.