proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by September 3, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10556 Medical Necessity and Contract Amendments Under Mental Health Parity

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medical Necessity and Contract Amendments Under Mental Health Parity; *Use:* Upon request, regulated entities must provide a medical necessity disclosure. Receiving this information will enable potential and current enrollees to make more educated decisions given the choices available to them through their plans and may result in better treatment of their mental health or substance use disorder (MH/SUD) conditions. States use the information collected and reported as part of its contracting process with managed care entities, as well as its compliance oversight role. In states where a Medicaid Managed Care Organization (MCO) is responsible for providing the full scope of medical/surgical and MH/SUD services to beneficiaries, the state will review the parity analysis provided by the MCO to confirm that the MCO benefits are in compliance. CMS uses the information collected and reported in an oversight role of State Medicaid managed care programs. *Form Number:* CMS–10556 (OMB control number: 0938–1280); *Frequency:* Once and occasionally; *Affected Public:* Individuals and households, the Private sector, and State, Local, or Tribal Governments; *Number of Respondents:* 47,468,596; *Total Annual Responses:* 285,444; *Total Annual Hours:* 48,057. (For policy questions regarding this collection contact Juliet Kuhn at 410–786–2480.)

Dated: June 27, 2019.

William N. Parham, III,

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

[FR Doc. 2019–14131 Filed 7–2–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2809]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Patient Engagement Advisory Committee (the Committee). The general function of the Committee is to provide advice to the Commissioner, or designee, on complex issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will be held on September 10, 2019, from 8 a.m. to 5:30 p.m.

ADDRESSES: Holiday Inn Gaithersburg, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900; additional information is available online at *https://www.ihg.com/holidayinn/hotels/us/en/gaithersburg/wasrv/hoteldetail.* Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, *letise.williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly

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.