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:


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).
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/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.

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.

<table>
<thead>
<tr>
<th>Application No.</th>
<th>Drug</th>
<th>Applicant</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA 016983</td>
<td>Conray 30 (iothalamate meglumine) injection, 30%</td>
<td>Liebel-Flarsheim Company LLC, et al.</td>
</tr>
<tr>
<td>NDA 018972</td>
<td>Cordarone (amiodarone HCl) Tablets, 200 mg</td>
<td>Bausch Health US, LLC</td>
</tr>
<tr>
<td>NDA 019009</td>
<td>Maxair Inhaler (pirbuterol acetate inhalation aerosol), equivalent to (EQ) 0.2 mg base/inhalation.</td>
<td>Bausch Health US, LLC</td>
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</tbody>
</table>