Based on a review of the information collection since our last request for OMB approval, the estimated burden for the information collection reflects an overall increase in total hours and responses. We attribute this adjustment to an increase in the number of submissions received over the last few years and additional interest in the biosimilars program.

Dated: June 28, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–14265 Filed 7–2–18; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2490]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on August 7, 2018, from 8:30 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. 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/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2018–N–1073. The docket will close on August 6, 2018. Submit either electronic or written comments on this public meeting by August 6, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 6, 2018. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of August 6, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 24, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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–2018–N–2490 for “Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see the ADDRESSES section), 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.

• 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.” FDA 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 be made publicly available, you can provide this information on the cover sheet and not

### Table 1—Estimated Annual Reporting Burden

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<thead>
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<th>Application Type</th>
<th>Number of Respondents</th>
<th>Number of Responses per Respondent</th>
<th>Total Annual Responses</th>
<th>Average Burden per Response</th>
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1 There are no capital costs or operating and maintenance costs associated with this collection of information.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0369]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by August 2, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oirsubmission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0212. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Regulations Under the Federal Import Milk Act (FIMA)—21 CFR Part 1210

OMB Control Number 0910–0212—Extension

Under FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the