TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| Activity | FDA form No. | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|---|
| Submission of NSSP Compliance Documentation. | N/A | 13 | 1 | 13 | 0.25 (15 minutes) ..... | 3.25 |
| Total ..... | ..... | ..... | ..... | ..... | ..... | 231.25 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates (Form FDA 3038) annually, or an average of 57 responses per respondent. We estimate that it takes a respondent an average of 6 minutes or 0.1 hour to complete each form for a total burden of 228 hours (2,280 submissions × 0.10 hours). This estimate is based on our experience with this information collection and the number of certificates received in the past 3 years, which has remained constant.

In order to gain equivalence recognition by the EC, we estimate that respondents will make a one-time submission of documents demonstrating NSSP compliance. We estimate that 13 respondents will each submit 1 response, for a total of 13 responses. We estimate that each response will take 15 minutes, or 0.25 hour, for an annual total of 3.25 hours (13 responses × 0.25 hour).

Dated: April 18, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–08174 Filed 4–23–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–N–3458]**

### Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of the Comment Period

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

**ACTION:** Notice; request for data and information; reopening of the comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is reopening the comment period provided in the notice entitled ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information'' that appeared in the **Federal Register** of December 7, 2018. That notice announced the establishment of a docket to obtain data, information, and comments that will assist the Agency in assessing the safety and effectiveness of food handler antiseptic drug products (*i.e.,* antiseptic hand washes or rubs intended for use in food handling settings) for over-the-counter human use. The Agency is taking this action to allow interested persons additional time to submit comments, data, or information.

**DATES:** FDA is reopening the comment period on the notice published on December 7, 2018 (83 FR 63168). Submit either electronic or written comments by July 23, 2019.

**ADDRESSES:** You may submit comments, data, or information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 23, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 23, 2019. 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.

*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–3458 for ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information; Reopening of Comment Period.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' The Agency 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 to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Pranvera Ikonomi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5418, Silver Spring, MD 20993–0002, 240–402–0272.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 7, 2018 (83 FR 63168), FDA published a notice entitled ''Food Handler Antiseptic Drug Products for Over-the-Counter Human Use; Request for Data and Information'' with a 60-day comment period to obtain data, information, and comments relating to the safety and effectiveness of food handler antiseptics. Following publication of the December 7, 2018, notice, FDA received a request to allow interested persons additional time to comment. FDA is reopening the comment period until July 23, 2019. The Agency believes that an additional 90 days will allow adequate time for interested persons to respond to FDA's specific requests for comments.

Dated: April 18, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–08251 Filed 4–23–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–1317]**

### 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 June 6, 2019, from 8:30 a.m. to 4:30 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–2019–N–1317. The docket will close on June 5, 2019. Submit either electronic or written comments on this public meeting by June 5, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 5, 2019. 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 May 22, 2019, 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–2019–N–1317 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