end users interpret zero-day withdrawal period, or zero-day milk discard times statements found on new animal drug labeling. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the request for comments published August 9, 2019 (84 FR 39340). Submit either electronic or written comments by January 6, 2020.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 6, 2020. 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–2019–N–3019 for ''Transit Times to Slaughter Facilities, Milking Frequency, and Interpretation of Zero-Day Withdrawal Periods and Zero-Day Milk Discard Times Assigned to New Animal Drugs.'' 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:** Charli M. Long-Medrano, Center for Veterinary Medicine (HFV–150), Food and Drug Administration, 7500 Standish Pl., Rm. E340, Rockville, MD 20855, 240–402–0850, *Charli.Long-Medrano@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of August 9, 2019, FDA published a request for comments with a 60-day comment period to request comments on transit times to slaughter, milking frequency, and how end users interpret zero-day withdrawal period, or zero-day milk discard time statements found on new animal drug labeling. Comments on interpretation of these labeling statements will help to evaluate if our current approach to assigning zero-day withdrawal periods and zero-day milk discard times to new animal drugs is appropriate.

The Agency has received requests for a 90-day extension of the comment period for the request for comments. The requests convey concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the request for comments.

FDA has considered the requests and is extending the comment period for the request for comments for 90 days, until January 6, 2020. The Agency believes that a 90-day extension allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

Dated: September 5, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–19697 Filed 9–11–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. FDA–2018–N–3516, FDA 2019–N–0482, FDA–2012–N–0021, FDA–2018–N–4042, FDA–2011–D–0597, FDA–2018–N–4735, FDA–2019–N–0721, FDA–2013–N–1425, FDA–2018–D–3631, and FDA–2011–D–0689]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a

list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *http://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

| Title of collection | OMB control No. | Date approval expires |
|---|---|---|
| Disease Awareness and Prescription Drug Promotion on Television | 0910–0874 | 8/31/2021 |
| Reporting Associated with New Animal Drug Applications and Veterinary Master Files | 0910–0032 | 7/31/2022 |
| Substances Generally Recognized as Safe: Notification Procedure | 0910–0342 | 7/31/2022 |
| Establishing and Maintaining Lists of U.S. Product Manufacturers/Processors with Interest in Exporting CFSAN-Regulated Products | 0910–0509 | 7/31/2022 |
| Oversight of Clinical Investigations; A Risk-Based Approach to Monitoring | 0910–0733 | 7/31/2022 |
| Safety Labeling Changes; Implementation of the Federal Food, Drug, and Cosmetic Act | 0910–0734 | 7/31/2022 |
| Accreditation of Third Party Certification Bodies to Conduct Food Safety Audits and Issue Certifications | 0910–0750 | 7/31/2022 |
| Mitigation Strategies to Protect Food Against Intentional Adulteration | 0910–0812 | 7/31/2022 |
| Standards for the Growing, Harvesting, Packaging, and Holding of Produce for Human Consumption | 0910–0816 | 7/31/2022 |
| De Novo Classification Process (Evaluation of Automatic Class III Designation) | 0910–0844 | 8/31/2022 |

Dated: September 6, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–19779 Filed 9–11–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–3936]**

### Endocrinologic and Metabolic 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 Endocrinologic and Metabolic 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 November 14, 2019, from 8 a.m. to 5 p.m.

**ADDRESSES:** The meeting will be held at FDA's 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–3936. The docket will close on November 13, 2019. Submit either electronic or written comments on this public meeting by November 13, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 13, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 13, 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 October 30, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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*

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