enhance the safety and security of the pharmaceutical distribution supply chain. Stakeholders may comment on utilizing the product identifier for product tracing and the technical capabilities of the pharmaceutical distribution supply chain and the system attributes that are necessary to implement the requirements under section 582. The information gathered from the workshop participants and from the comments submitted to the docket for the public workshop will further inform FDA's development of its pilot project program under section 582(j) of the FD&C Act.

III. Registration for the Public Workshop

To request registration for the public workshop, provide your information including name, company or organization, address, telephone number, and email address to FDA at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm.* Registration requests should be received by March 11, 2016. FDA is limiting workshop attendance due to limited space. FDA may limit the number of participants from each organization based on space limitations. FDA recommends that each organization determine who should register for the workshop to represent his/her organization. This will help ensure that the workshop will have broad and varied representation across the pharmaceutical distribution supply chain. Registrants will receive confirmation of participation for the workshop from FDA by March 18, 2016. There is no registration fee for the public workshop. There will be no onsite registration. If registration reaches maximum capacity, FDA will post a notice closing registration for the workshop on FDA's Web site at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm.* If you need special accommodations due to a disability, please contact Daniel Bellingham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the public workshop.

IV. Webcasting of the Public Workshop

Portions of this public workshop will be recorded and Webcasted on the day of the workshop. Information for how to access the Webcast will be available at *http://www.fda.gov/Drugs/NewsEvents/ucm481767.htm* by March 29, 2016. The Webcast will be conducted in listening-mode only.

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02977 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0437]

Evaluation of the Safety of Drugs and Biological Products Used During Lactation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Evaluation of the Safety of Drugs and Biological Products used during Lactation.'' The purpose of this workshop is to provide a forum to discuss the current state and future directions of the collection of data on the potential risks to breastfed infants with maternal use of medications during lactation. The workshop will review current approaches to the collection of data when drugs are used or expected to be used during lactation. The workshop will also discuss and consider novel approaches to improve the quality and quantity of data, to inform of the potential risks of medication use during lactation, and to raise awareness and engage stakeholders about communication of safety information related to maternal use of medications during lactation.

DATES: The public workshop will be held on April 27, 2016, from 8 a.m. to 5 p.m.; and April 28, 2016, from 8 a.m. to 1 p.m. Registration closes on April 8, 2016. Submit electronic or written comments to the public docket by May 28, 2016.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–0437 for ''Evaluation of the Safety of Drugs and Biological Products used during Lactation; Public Workshop; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: For questions regarding the workshop, contact Denise Pica-Branco, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1732, FAX: 301–796–9858, *denise.picabranco@fda.hhs.gov;* or Denise Johnson-Lyles, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6169; FAX: 301–796–9858, *denise.johnson-lyles@fda.hhs.gov.*

Registration: Participation can be either in person attendance or by Webcast. There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at *lactation@fda.hhs.gov.* Please include: (1) First and last name, (2) contact phone or email address, (2) live attendance or via Webcast, (4) indicate if you plan to attend day 1, day 2, or both days. Registration closes on April 8, 2016. For those without Internet access, please contact Denise Pica-Branco or Denise Johnson-Lyles (see **FOR FURTHER INFORMATION CONTACT**) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco or Denise Johnson-Lyles (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has engaged with regulatory, academic, and industry experts to discuss the current state and future directions of the collection of data on the potential risks to breastfed infants with maternal use of medications during lactation. The first day of the workshop will focus on review and discussion of current approaches for the collection of data, and review and discussion of gaps in our present knowledge. The second day of the workshop will focus on consideration of novel approaches to improve the quality and quantity of data available to assess the safety of medications used during lactation as well as a review and discussion of strategies to communicate safety information related to maternal use of medications during lactation.

This workshop includes a public comment session. If you would like to present during this session, please identify the topic(s) you will address during the registration. FDA will do its best accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Following the close of registration, FDA will allot time for each presentation and notify presenters by April 21, 2016. Do not present or distribute commercial or promotional material during the workshop. Registered presenters should check in before the workshop begins.

II. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02967 Filed 2–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Bioequivalence Recommendations for Cyclosporine; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry on cyclosporine ophthalmic emulsion entitled ''Draft Guidance on Cyclosporine.'' The recommendations provide specific guidance on the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for cyclosporine ophthalmic emulsion. This draft guidance is a revised version of a previously issued draft guidance on the same subject.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by April 18, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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