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

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–2007–P–0369 for ''Draft Guidance on Cyclosporine.'' 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.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Xiaoqiu Tang, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry, ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. This notice announces the availability of revised draft BE recommendations for cyclosporine ophthalmic emulsion.

FDA initially approved new drug application 050790 for RESTASIS (cyclosporine ophthalmic emulsion), 0.05% in December 2002. There are no approved ANDAs for this product. In June 2013, we issued a draft guidance for industry on BE recommendations for generic cyclosporine ophthalmic emulsion.

Allergan, Inc., manufacturer of the reference listed drug, RESTASIS, submitted a citizen petition in February 2014 challenging the Agency's initial BE recommendations for generic cyclosporine ophthalmic emulsion. We responded to that petition on November 20, 2014 (Docket No. FDA–2014–P–0304). The following month, Allergan submitted a second citizen petition challenging the Agency's initial BE recommendations. In April 2015, FDA received a third citizen petition on its initial BE recommendations from Physical Pharmaceutica LLC. FDA has reviewed the issues raised by Allergan and Physical Pharmaceutica and is responding to their petitions (Docket Nos. FDA–2015–P–0065 and FDA–2015–P–1404).

In addition, we are now issuing a revised draft guidance for industry on BE recommendations for generic cyclosporine ophthalmic emulsion (''Draft Guidance on Cyclosporine'').

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for cyclosporine ophthalmic emulsion. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: February 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–02975 Filed 2–12–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0236]

Nonallergic Rhinitis: Developing Drug Products for Treatment; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.