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(f) 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. 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, 301–796–4732, FAX: 301–
796–9858, denise.picabranco@
fdc.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
calculate 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 this session. If you
would like to present during this session,
please contact Denise Pica-Branco or
Denise Johnson-Lyles (see FOR
FURTHER INFORMATION CONTACT) to
register. Onsite registration will not be
available.
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 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