New Hampshire Ave., Bldg. 71, Rm. 3128, 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 guidance document.


SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Bacterial Vaginosis: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the development of new topical and systemic drugs for the treatment of BV. This guidance finalizes the draft guidance of the same name issued on July 14, 2016 (81 FR 45509). Changes in this final guidance include clarification about the timing of the primary efficacy endpoints, which are based on the intended treatment duration and the half-life of the topical or systemic drug. Minor edits were included for better clarity, such as guidance applicability to both topical and systemic drugs. This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Bacterial Vaginosis: Developing Drugs for Treatment.” It does not establish any regulatory or legal requirements for industry or the public. This guidance includes an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access


Dated: July 29, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

[FR Doc. 2019–16425 Filed 7–31–19; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1562]

Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment.” The purpose of this guidance is to assist sponsors in the development of new drugs for the treatment of uncomplicated urinary tract infections. This guidance finalizes the draft guidance of the same name issued May 10, 2018.

DATES: The announcement of the guidance is published in the Federal Register on August 1, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2018–D–1562 for “Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment”. Received comments 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/
fdys/pk/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.
You may submit comments on any
guidance at any time (see 21 CFR
10.115(g)(5)).
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 guidance document.
FOR FURTHER INFORMATION CONTACT:
Joseph Toerner, Center for Drug
Evaluation and Research, Food and
Drug Administration, 10903 New
Hampshire Ave., Bldg. 22, Rm. 6244,
Silver Spring, MD 20993–0002, 301–
796–1400.
I. Background
FDA is announcing the availability of
a final guidance for industry entitled
“Uncomplicated Urinary Tract
Infections: Developing Drugs for
Treatment.” The purpose of this
guidance is to assist sponsors in the
development of new drugs for the
treatment of uncomplicated urinary
tract infections.
This guidance finalizes the draft
guidance of the same name issued May
28, 2018 (83 FR 21784). There were no
comments regarding the draft guidance
submitted to the public docket. We
made some editorial changes made in
the final guidance primarily for
clarification.
Issuance of this guidance fulfills a
portion of the requirements of Title VIII,
section 804, of the Food and Drug
Administration Safety and Innovation
Act (FDARA), which requires FDA to review and, as appropriate,
revise not fewer than three guidance
documents per year for the conduct of
clinical trials with respect to
antibacterial and antifungal drugs.
This guidance is being issued
consistent with FDA’s good guidance
practices regulation (21 CFR 10.115).
The guidance represents the current
thinking of FDA on “Uncomplicated
Urinary Tract Infections: Developing
Drugs for Treatment.” It does not
establish any rights for any person and
is not binding on FDA or the public.
You can use an alternative approach if
it satisfies the requirements of the
applicable statutes and regulations. This
guidance is not subject to Executive
Order 12866.
II. Paperwork Reduction Act of 1995
This guidance refers to previously
approved collections of information that
are subject to review by the Office of
Management and Budget (OMB) under
the Paperwork Reduction Act of 1995
(44 U.S.C. 3501–3520). The collections
of information in 21 CFR parts 312, 314,
and 601 have been approved under
OMB control numbers 0910–0014,
0910–0015, and 0910–0338,
respectively.
III. Electronic Access
Persons with access to the internet
may obtain the draft guidance at either
http://www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm or https://
www.regulations.gov.
Dated: July 29, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019–16423 Filed 7–31–19; 8:45 am]
BILLING CODE 4164–01–P
DEPARTMENT OF HEALTH AND
HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2019–D–3132]
General Clinical Pharmacology
Considerations for Neonatal Studies
for Drugs and Biological Products;
Draft Guidance for Industry;
Availability
AGENCY: Food and Drug Administration,
HHS.
ACTION: Notice of availability.
SUMMARY: The Food and Drug
Administration (FDA or Agency) is
announcing the availability of a draft
guidance for industry entitled “General
Clinical Pharmacology Considerations
for Neonatal Studies for Drugs and
Biological Products.” This draft
guidance is intended to assist sponsors
of new drug applications (NDAs),
biologics license applications (BLAs) for
therapeutic biologics, and supplements
who are planning to conduct clinical
studies in neonatal populations. The
issuance of this draft guidance on
clinical pharmacology considerations
for neonatal studies for drugs and
biological products is stipulated under
the FDA Reauthorization Act of 2017
(FDARA).
DATES: Submit either electronic or
written comments on the draft guidance
by October 30, 2019 to ensure that the
Agency considers your comment on this
draft guidance before it begins work on
the final version of the guidance.
ADDRESSES: You may submit comments
on any guidance at any time 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–