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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this 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: Kimberly Struble, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6374, Silver Spring MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.” The purpose of this guidance is to provide to sponsors nonclinical and clinical recommendations specific to the development of systemic drug products, with a focus on long-acting systemic drug products (including small molecules and monoclonal antibodies) for the prevention of sexually acquired human immunodeficiency virus-1 (HIV–1) infection. Specifically, this guidance addresses FDA’s current thinking regarding the overall development program and clinical trial designs to support the development of systemic drug products for the prevention of HIV–1 infection. FDA recognizes the challenges in evaluating systemic drug products for the prevention of sexually acquired HIV–1 infection. FDA continues to evaluate possible approaches for the development of new therapies for HIV prevention and will update this guidance if new information becomes available.

This guidance finalizes the draft guidance of the same name issued on June 14, 2018 (83 FR 27782). All public comments received on the draft guidance have been considered and the guidance has been revised as appropriate, along with a few editorial changes.

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 “Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.” 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 collection of information submitted under 21 CFR part 312 has been approved under OMB control number 0910–0014. The collection of information submitted under 21 CFR part 314 has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or https://www.regulations.gov.

Dated: March 14, 2019.

Lowell J. Schiller,
Acting Associate Commissioner for Policy.
[FR Doc. 2019–05231 Filed 3–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1638]

Pediatric Human Immunodeficiency Virus Infection: Drug Product Development 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 “Pediatric HIV Infection: Drug Product Development for Treatment.” The purpose of this guidance is to provide general recommendations on the development of antiretroviral drug products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients. The guidance addresses when to initiate pediatric formulation development and begin pediatric studies and offers approaches for enrollment of subjects into pediatric studies to help facilitate drug product development. This guidance incorporates the comments received for and finalizes the draft guidance for industry “Pediatric HIV Infection: Drug Development for Treatment” issued on May 14, 2018.


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
detailed in “Instructions.”
Instructions: All submissions received
must include the Docket No. FDA–
2018–D–1638 for “Pediatric HIV
Infection: Drug Product Development
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/
 fdsys/pkg/FR-32015-309-318/pdf/2015-
32389.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 this 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; or the Office of Communication,
Outreach, and Development, Center for
Biologics Evaluation and Research,
Food and Drug Administration, 10903
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.
FOR FURTHER INFORMATION CONTACT:
Yodit Belew, Center for Drug Evaluation
and Research, Food and Drug
Administration, 10903 New Hampshire
Ave., Bldg. 22, Rm., 6322, Silver Spring,
MD 20993–0002; or Stephen Ripley,
Center for Biologics Evaluation and
Research, Food and Drug
Administration, 10903 New
Hampshire Ave., Bldg. 71, Rm. 7301,
Silver Spring, MD 20993–0002, 240–
402–7911.
SUPPLEMENTARY INFORMATION:
I. Background
FDA is announcing the availability of
a guidance for industry entitled
“Pediatric HIV Infection: Drug Product
Development for Treatment.” The
purpose of this guidance is to provide
general recommendations on the
development of antiretroviral drug
products for the treatment of HIV
infection in pediatric patients. The
guidance addresses when to initiate
pediatric formulation development and
begin pediatric studies and offers
approaches for enrollment of subjects
into pediatric studies to help expedite
drug product development. This
guidance incorporates the comments
received for and finalizes the draft
guidance of the same name issued on
May 14, 2018 (83 FR 22270). Changes
made to the draft guidance took into
consideration written and verbal
comments received. In addition to
editorial changes primarily for
clarification, the major changes are as
follows:
• Inclusion of a statement to address
neonates and
• Considerations on how to analyze
the adolescent data when adolescents
are included in the adult phase 3
clinical trials.
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 “Pediatric HIV
Infection: Drug Product Development
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 part 312, 21
CFR part 314, and 21 CFR 201.56 and
201.57 have been approved under OMB
control numbers 0910–0014, 0910–0001,
and 0910–0572, respectively.
III. Electronic Access
Persons with access to the internet
may obtain the guidance at https://
www.fda.gov/Drugs/Guidance
ComplianceRegulatoryInformation/
Guidances/default.htm, https://
www.fda.gov/BiologicsBloodVaccines/
GuidanceCompliance
RegulatoryInformation/default.htm, or
Dated: March 14, 2019.
Lowell J. Schiller,
Acting Associate Commissioner for Policy.
[FR Doc. 2019–05232 Filed 3–19–19; 8:45 am]