

Estimated Total Annual Burden Hours: 5,211.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: OPREinfocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-1638]

Pediatric HIV Infection: Drug Development for Treatment; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Pediatric HIV Infection: Drug Development for Treatment.” This guidance provides general recommendations on the development of drug products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients (birth to younger than 17 years of age).

DATES: Submit either electronic or written comments on the draft guidance by July 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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-2018-D-1638 for “Pediatric HIV Infection: Drug Development for Treatment; Draft Guidance for Industry; Availability.” 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-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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 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 draft 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, 301-796-1500; 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 draft guidance for industry entitled "Pediatric HIV Infection: Drug Development for Treatment." This draft guidance provides general recommendations on the development of products for the treatment of human immunodeficiency virus (HIV) infection in pediatric patients (birth to younger than 17 years of age), including recommendations on when sponsors should initiate pediatric formulation development and begin pediatric studies to evaluate antiretroviral drug products for the treatment of HIV infection.

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 current thinking of FDA on drug development for treatment of pediatric HIV infection. 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. Electronic Access

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

Dated: May 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Membership To Serve on the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Council on Graduate Medical Education (COGME). COGME provides advice and recommendations to the Secretary of HHS; the Senate Committee on Health, Education, Labor and Pensions; and the U.S. House of Representatives Committee on Energy and Commerce on matters concerning the supply and distribution of physicians in the United States, physician workforce trends, training issues, financing policies, and other matters of significance related to physician workforce and graduate medical education.

DATES: The agency will accept nominations on a continuous basis.

ADDRESSES: Nomination packages may be mailed to Advisory Council Operations, Bureau of Health Workforce, HRSA, Room 11W45C, 5600 Fishers Lane, Rockville, Maryland 20857 or submitted electronically by email to: BHWAdvisoryCouncilFRN@hrsa.gov.

FOR FURTHER INFORMATION CONTACT: Kennita R. Carter, MD, Designated Federal Official, COGME at 301-945-3505 or email at kcarter@hrsa.gov. A copy of the current COGME charter, membership, and reports can be obtained by accessing the COGME website <https://www.hrsa.gov/advisorycommittees/bhpradvisory/cogme/>.

SUPPLEMENTARY INFORMATION: COGME encourages entities providing graduate medical education to conduct activities to voluntarily achieve the recommendations of COGME; develops, publishes, and implements performance measures and longitudinal evaluations; and recommends appropriation levels for certain Public Health Service Act (PHSA) Title VII programs. Meetings take place twice a year.

Nominations: HRSA is requesting nominations for voting members of COGME to include representatives of practicing primary care physicians, national and specialty physician organizations, foreign medical graduates, medical student and house staff associations, schools of allopathic and osteopathic medicine, public and private teaching hospitals, and representatives of health insurers, business, and labor. Additionally, HRSA encourages nominations of medical students, residents, and/or fellows. Members receive appointments based on their competence, interest, and knowledge of the mission of the profession involved.

The Secretary of HHS will consider nominations of all qualified individuals within the areas of subject matter expertise noted above. In making such appointments, the Secretary shall ensure a broad geographic representation of members and a balance between urban and rural educational settings.

Professional organizations, employers, or colleagues may nominate one or more qualified persons for membership. Individuals selected for appointment to COGME will be invited to serve for 4 years. COGME members are appointed as special government employees and receive a stipend and reimbursement for per diem and travel expenses incurred for attending meetings and/or conducting other business on behalf of COGME, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service.

To evaluate possible conflicts of interest, individuals selected for consideration for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. The selected candidates must fill out the U.S. Office of Government Ethics (OGE) Confidential Financial Disclosure Report, OGE Form 450. Disclosure of this information is necessary to determine if the selected candidate is involved in any activity that may pose a potential conflict with their official duties as a member of the Committee.

A nomination package should include the following information for each nominee: (1) A letter of nomination from an employer, a colleague, or a professional organization stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of COGME), and the nominee's field(s) of expertise; (2) a letter of interest from the nominee stating the reasons they would like to serve on COGME; (3) a biographical sketch of the nominee, including a copy of his/her curriculum vitae and his/her contact information (address, daytime telephone number, and email address); and (4) the name, address, daytime telephone number, and email address where the person nominating the individual can be contacted.

HRSA will collect and retain nomination packages to create a pool of possible future COGME voting members. When a vacancy occurs, HRSA may review nomination packages from the appropriate category and may contact nominees at that time.