coordinating with public and private organizations in the planning and development of comprehensive and coordinated services and supports.

BG.10 Organization. CRO is directed by a Deputy Administrator and includes a coordinating central office and Regional Support Centers around the country. The Center for Regional Operations includes the following components: Office of the Deputy Administrator for Regional Operations (BHA) Regional Support Centers (BHB1–BHB10)

BG.20 Functions.

1. Office of the Deputy Administrator of Regional Operations (BHA). The Office of the Deputy Administrator of Regional Operations directs and coordinates the work of all ACL regional operations and activities and supervises the ten Regional Administrators who each serve as a liaison to their assigned region.

The Regional Support Centers (BHB1–BHB10) serve as the focal point for the coordination of ACL programs within their designated HHS region, and support state and local efforts to improve community living for older adults and persons with disabilities. Represent the agency within the region, providing information for, and helping to advance the development of, national programs serving older adults and persons with disabilities. Serve as advocates for ACL stakeholders to other federal agencies in their geographic jurisdictions; advise, consult and cooperate with each federal agency proposing or administering programs or services that affect ACL stakeholders; coordinate and assist public (including federal, state, tribal and local agencies) and private organizations in the planning and development of comprehensive and coordinated services; and conduct education of officials and the broader community to ensure understanding of the need for community-based services and supports for older adults and people with disabilities.

Advise the Deputy Administrator on problems and progress of programs; evaluate the effectiveness of programs and services in the regions and recommend changes that would improve program operations and enhance effectiveness; and provide guidance to agencies and grantees in applications of policy to specific operational issues requiring resolution. Facilitate interagency cooperation at the federal, regional, state and tribal levels to enhance resources and assistance available to older adults and persons with disabilities. Disseminate and provide technical assistance regarding program guidelines and developments to state agencies, tribal organizations, and local community service providers.

IX. *Delegations of Authority:* All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegation, provided they are consistent with this reorganization.

X. *Funds, Personnel and Equipment:* Transfer of functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies and other resources.

This reorganization will be effective upon date of signature.

Dated: May 2, 2019.

Alex M. Azar II,

Secretary.

[FR Doc. 2019–09444 Filed 5–8–19; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4525]

Clinical Lactation Studies: Considerations for Study Design; 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 ''Clinical Lactation Studies: Considerations for Study Design.'' This guidance reflects FDA's current recommendations to sponsors regarding lactation studies during drug development. This guidance provides recommendations to facilitate the conduct of lactation studies. Such studies can inform breastfeeding with drug use recommendations included in the *Lactation* subsection of labeling. The recommendations in this guidance also reflect discussions from the 2007 Pediatric Advisory Committee meeting and the 2016 Lactation Workshop, which considered how data from clinical lactation studies can inform the safety of a drug when used during lactation. This guidance replaces the draft guidance for industry entitled ''Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling'' issued February 2005.

DATES: Submit either electronic or written comments on the draft guidance by July 8, 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–2018–D–4525 for ''Clinical Lactation Studies: Considerations for Study Design.'' 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 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jian Wang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm 5309, Silver Spring, MD 20993–0002, 301–796–3846; 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 ''Clinical Lactation Studies: Considerations for Study Design.'' This guidance reflects FDA's current recommendations regarding lactation studies during drug development. This guidance provides recommendations to facilitate the conduct of lactation studies. Such studies can inform breastfeeding with drug use recommendations included in the *Lactation* subsection of labeling. The recommendations in this guidance also reflect discussions at the 2007 Pediatric Advisory Committee meeting (see *https://wayback.archive-it.org/7993/20170403222238/https://www.fda.gov/ohrms/dockets/ac/oc07.htm#pac*) and the 2016 Lactation Workshop (see *https://www.fda.gov/Drugs/NewsEvents/ucm486761.htm*), which considered how data from clinical lactation studies can inform the safety of a drug when used during lactation. However, this guidance does not address specific lactation labeling recommendations because these topics are addressed in 21 CFR 201.57(c)(9)(ii) and the draft guidance for industry ''Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products—Content and Format'' (available at *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm425398.pdf*). This guidance replaces the draft guidance for industry entitled ''Clinical Lactation Studies—Study Design, Data Analysis, and Recommendations for Labeling'' issued February 8, 2005 (70 FR 6697).

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 ''Clinical Lactation Studies: Considerations for Study Design.'' 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 draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 in 21 CFR part 314, including the submission of labeling under §§ 314.50(e)(2)(ii) and 314.50(l)(1)(i), has been approved under OMB control number 0910–0001. The submission of prescription drug labeling under §§ 201.56 and 201.57 has been approved under OMB control number 0910–0572. The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

III. Electronic Access

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

Dated: May 3, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09528 Filed 5–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1263]

Submitting Documents Using Real-World Data and Real-World Evidence to the Food and Drug Administration for Drugs and Biologics; 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 ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics.'' This draft guidance is intended to encourage sponsors and applicants who are using real-world data (RWD) to generate real-world evidence (RWE) as part of their regulatory submissions to provide certain information to FDA so that FDA can internally track the submissions. The purpose of this guidance is to provide instructions on how to document that a submission includes RWE.