Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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 (CBER), 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: Richard Whitehead, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3362, Silver Spring, MD 20993–0002, 301–796–4945; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.'' This guidance addresses FDA's current recommendations on clinical trials for drugs being developed for the treatment of celiac disease as an adjunct to a gluten-free diet in adults, including recommendations for eligibility criteria, trial design features, efficacy evaluations, clinical outcome assessments, and safety assessments.

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 ''Celiac Disease: Developing Drugs for Adjunctive Treatment to a Gluten-Free Diet.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 50 and 58, 21 CFR parts 312 and 314, and 21 CFR part 601 have been approved under OMB control numbers 0910–0130, 0910–0014, 0910–0001, and 0910–0338 respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, or https://www.regulations.gov.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08116 Filed 4–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4367]

Bioavailability Studies Submitted in NDAs or INDs—General Considerations; 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 ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' This guidance provides recommendations to sponsors planning to include bioavailability (BA) information for drug products in investigational new drug applications (INDs), new drug applications (NDAs), and NDA supplements. This guidance finalizes the draft guidance of the same title issued on February 26, 2019. This guidance also replaces the draft guidance entitled ''Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations'' issued March 2014.

DATES: The announcement of the guidance is published in the **Federal Register** on April 15, 2022.

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–4367 for ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' 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, 240–402–7500.

• 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.govinfo.gov/content/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, 240–402–7500.

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: Dakshina Chilukuri, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1515, *Dakshina.Chilukuri@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Bioavailability Studies Submitted in NDAs or INDs—General Considerations.'' Determining the BA of formulations is critical during the life cycle of drug products and aids in the FDA's evaluation of the safety and effectiveness of a product in INDs, NDAs, or NDA supplements. This guidance provides recommendations to sponsors and applicants planning to include BA information for drug products in INDs, NDAs, and NDA supplements. This guidance contains recommendations on how to meet the BA requirements set forth in part 320 (21 CFR part 320) as they apply to dosage forms intended for oral administration. The guidance is also applicable to non-orally administered drug products when it is appropriate to rely on systemic exposure measures to determine the BA of a drug (*e.g.,* transdermal delivery systems and certain rectal and nasal drug products). The guidance provides recommendations on conducting relative BA studies during the investigational period for an NDA and bioequivalence (BE) studies during the postapproval period for certain changes to drug products with an approved NDA.

This guidance finalizes the draft guidance entitled ''Bioavailability Studies in NDAs or INDs—General Considerations'' issued on February 26, 2019 (84 FR 6148) (the 2019 draft guidance). When FDA issued the 2019 draft guidance, FDA explained that the 2019 draft guidance revised and replaced the draft guidance entitled ''Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations'' issued on March 2014 (the 2014 draft guidance) (84 FR 6148). FDA considered comments received on the 2014 draft guidance in preparing the 2019 draft guidance. FDA likewise considered comments received on the 2019 draft guidance as this guidance was finalized. Changes from the 2019 draft guidance to the final guidance include the following: (1) Specifying that individual pharmacokinetic profiles will be considered for products with complex release characteristics; (2) clarifying that if the drug labeling specifies the drug to be taken with food but does not elaborate on the fed conditions, the sponsor should use a high-fat meal as the fed condition; (3) adding statistical approaches for dissolution; (4) clarifying that enzymes can be added to the dissolution medium to better understand the effect of over-encapsulation on drug release; and (5) removing the 10 percent alcohol level for dose-dumping studies. In addition, editorial changes were made to improve clarity.

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 ''Bioavailability Studies in NDAs or INDs—General Considerations.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA.

The collections of information in 21 CFR part 314 relating to the submission of new drug applications, abbreviated new drug applications, and supplemental applications and the submission of requests to waive in vivo BA and BE requirements have been approved under OMB control number 0910–0001.

The collections of information in 21 CFR part 312 relating to the submission of investigational new drug applications and BA/BE studies or pharmacogenomic data and the collections of information in part 320 for drug safety reporting have been approved under OMB control numbers 0910–0014 and 0910–0291.

The collections of information in 21 CFR parts 50 and 56 relating to the protection of human subjects and investigational review boards have been approved under OMB control number 0910–0130.

The collections of information in 21 CFR 201.56 and 201.57 for the Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs*, *https://www.regulations.gov*, or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08114 Filed 4–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee), authorized under section 1111(g) of the Public Health Service Act, and the Federal Advisory Committee Act, on Thursday, May 12, 2022, and Friday, May 13, 2022. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Thursday, May 12, 2022, from 10:00 a.m. to 3:20 p.m. Eastern Time (ET) and Friday, May 13, 2022, from 10:00 a.m. to 12:40 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at *https://www.achdncmeetings.org/registration/* by the deadline of 12:00 p.m. ET on May 11, 2022. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the May 12–13, 2022, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

(1) Final evidence-based review report on the guanidinoacetate methyltransferase (GAMT) deficiency condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend the Secretary add GAMT deficiency to the RUSP;

(2) An update on the Krabbe disease condition nomination;

(3) A possible vote on whether to move Krabbe disease forward to full evidence-based review;

(4) A presentation on homocystinuria newborn screening status; and

(5) A presentation on the Newborn Screening Family Education Program.

The agenda for this meeting includes a potential vote which may lead to a decision to recommend a nominated condition (GAMT deficiency) to the RUSP. In addition, as noted in the agenda items, the Committee may hold a vote on whether or not to recommend a nominated condition (Krabbe disease) to full evidence-based review, which may lead to a recommendation to add or not add a condition/conditions to the RUSP at a future time.

Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website listed above.

Members of the public will have the opportunity to provide comments. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: Members of the public registered to submit oral