contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 10, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24095 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0112]

Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; 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 ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry.'' This guidance is intended to provide a framework for considering whether and what type of long-term neurologic, sensory, and developmental evaluations could be useful in supporting a determination of safety of an FDA-regulated ''medical product'' (*i.e.,* drug, biological product, or medical device) for use in neonates. Although short-term safety evaluations may be appropriate for adults or other populations, such evaluations may not identify important adverse events in the neonatal population, as medical treatment during the neonatal period coincides with a time of critical growth and physiologic development and latent effects may not be evident until later in life following early-life exposures. Consideration of the potential for long-term neurologic, sensory, and developmental effects in the neonatal population early in a development program is important for establishing safety of a medical product intended for use in neonates. This guidance finalizes the draft guidance of the same title issued on February 13, 2023.

DATES: The announcement of the guidance is published in the **Federal Register** on October 18, 2024.

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–2022–D–0112 for ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry.'' 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; 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; or

Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, 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: An Massaro, Office of Pediatric Therapeutics, Office of Clinical Policy and Programs, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, 5th Floor, Silver Spring, MD 20993–0002, 301–467–8507; Gerri Baer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5399, Silver Spring, MD 20993–0002, 240–402–2865; James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Silver Spring, MD 20993–0002, 240–402–5923; and Vasum Peiris, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–6089.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry.''

Treatment with medical products during the neonatal period coincides with a time of critical growth and physiologic development. Although short-term safety evaluations may be appropriate for adults or other populations, such short-term evaluations may not identify important adverse events in the neonatal population, as latent effects may follow early-life exposures. Historically, most medical products used to treat neonates and young infants were not approved for use in these populations, and thus have not undergone comprehensive evaluation of safety or efficacy for use in neonates.

Neonates should have the same access as other populations to medical products that have been adequately evaluated for optimal dosing, efficacy, and safety. There are unique conditions that occur in term or preterm neonates that do not have analogous clinical conditions in older populations. As products are developed for unique neonatal conditions, first-in-human studies may occur in neonates, and these development programs should demonstrate long-term neurologic, sensory, and developmental safety. Clinical investigators and sponsors of neonatal studies should consider both the potential short- and long-term effects of an investigational therapy, whether the therapy has been approved for a similar indication in an older population or whether being developed for a new indication specific to the neonatal population.

This guidance will discuss general, patient-specific and product-specific considerations that impact the evaluation of whether and what type of long-term follow-up assessment should be considered. Types of follow-up assessments, ranging from neurodevelopmental screening through a comprehensive neurodevelopmental evaluation, which domains of assessment may be most pertinent, and the timing and duration of assessment are discussed.

This guidance finalizes the draft guidance entitled ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry'' issued on February 13, 2023 (88 FR 9296). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include:

- The background section of the guidance addresses the recommended minimum duration of follow-up and notes that this will depend on different population- and product-specific factors as discussed throughout the guidance.
- In the section of the guidance that addresses product-specific considerations when determining whether long-term neurodevelopmental safety evaluations should be conducted, new text was added about the impact of the route of product administration.
- In the section of the guidance that addresses general considerations when developing a plan to evaluate long-term neurodevelopmental safety, new text was added about planning for clinical referral.
- New text was also added to the first paragraph of the section of the guidance entitled ''What to Measure, When, and for How Long'' that clarifies that the protocol should specify whether assessments are conducted as part of standard clinical care or for research-related purposes only. The new text also clarifies that for research-related interventions, the benefit-risk determination should be performed to ensure that the procedure is ethically permissible.

In addition, editorial changes were made to improve clarity noting that this guidance does not address gene therapy or genomic medical interventions.

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 ''Considerations for Long-Term Clinical Neurodevelopmental Safety Studies in Neonatal Product Development; Guidance for Industry.'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information for submission of investigational new drug applications, 21 CFR part 312, have been approved under 0910–0014. The collections of information for submission of new drug applications, 21 CFR part 314, have been approved under 0910–0001. The collections of information for submission of biologic license applications, 21 CFR part 601, have been approved under 0910–0338. The collections of information for submission of premarket notifications, 21 CFR part 807, subpart E; investigational device exemptions, 21 CFR part 812; premarket approval applications, part 814 (21 CFR part 814), subparts A through E; humanitarian device exemptions, part 814, subpart H; De Novo classification requests, 21 CFR part 860, subpart D; and the Q-submission Program, in FDA's guidance entitled ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program,'' have been approved under OMB control numbers 0910–0120, 0910–0078, 0910–0231, 0910–0332, 0910–0844, and 0910–0756, respectively.

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.fda.gov/regulatory-information/search-fda-*

guidance-documents, or *https://www.regulations.gov.*

Dated: October 10, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24108 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the National Advisory Council on Migrant Health; Amended Notice of Meeting

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

ACTION: Notice; amended notice of meeting.

SUMMARY: HRSA published a notice in the **Federal Register** of July 23, 2024, concerning a meeting of the National Advisory Council on Migrant Health on October 22, 2024, and October 23, 2024. The notice states the meeting will be held in-person and via webinar. However, due to the impact of recent hurricanes on council members, this meeting now will be held via webinar only on Zoom.

FOR FURTHER INFORMATION CONTACT: Liz Rhee, National Advisory Council on Migrant Health Designated Federal Official, Office of Policy and Program Development, Bureau of Primary Health Care, HRSA, 5600 Fishers Lane, Rockville, MD 20857; 301–443–1082 or *hrsabphcoppdnacmh@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Amended Notice of Meeting

In the **Federal Register** Notice of July 23, 2024, FR Doc. 2024–16119, page 59744, column 1, section 2, paragraph 3, amend the sentences ''This meeting will be held in-person and via webinar. The address of the meeting is 5600 Fishers Lane, Rockville, MD 20857'' to read: ''This meeting will be held via webinar only.'' In paragraph 8, delete the following sentences: ''Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.''

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2024–24165 Filed 10–17–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Advisory Committee on Blood and Tissue Safety and Availability

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) has been renewed.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the ACBTSA; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Tower Building, 1101 Wootton Parkway, Rockville, MD 20852. Phone: (202) 795–7608. Email: *ACBTSA@hhs.gov.*

SUPPLEMENTARY INFORMATION: The ACBTSA is a non-discretionary federal advisory committee. The ACBTSA is authorized under 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App), which sets forth standards for the formation and use of advisory committees. The ACBTSA advises, assists, consults with, and makes policy recommendations to the Secretary, through the Assistant Secretary for Health, regarding broad responsibilities related to the safety of blood, blood products, tissues, and organs. For solid organs and blood stem cells, the Committee's work is limited to policy issues related to donor derived infectious disease complications of transplantation.

To carry out its mission, the ACBTSA provides advice to the Secretary through the Assistant Secretary for Health on a range of policy issues which includes: (1) identification of public health issues through surveillance of blood and tissue safety issues with national biovigilance data tools; (2) identification of public health issues that affect availability of blood, blood products, and tissues; (3) broad public health, ethical, and legal issues related to the safety of blood, blood products, and tissues; (4) the impact of various economic factors (*e.g.,* product cost and supply) on safety and availability of blood, blood products, and tissues; (5) risk communications related to blood transfusion and tissue transplantation; and (6) identification of infectious disease transmission issues for blood, organs, blood stem cells and tissues.

On September 25, 2024, the Secretary approved for the ACBTSA charter to be renewed. Renewal of the Committee's charter gives authorization for the Committee to continue to operate until October 9, 2026.

A copy of the ACBTSA charter is available on the Committee's website at *https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/charter/index.html.*

Dated: October 3, 2024.

James J. Berger,

DFO, Advisory Committee on Blood and Tissue Safety and Availability, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2024–24133 Filed 10–17–24; 8:45 am]

BILLING CODE 4150–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

DATES: The meeting will be held on Tuesday, October 22, 2024, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP website as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may