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

public comments on GAMT deficiency are tentatively scheduled to provide their statements on Thursday, May 12, 2022. Members of the public registered to provide statements on all other newborn screening related topics are tentatively scheduled for Friday, May 13, 2022. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, May 6, 2022.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2022–08053 Filed 4–14–22; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Comments on Scientific Questions To Be Examined To Support the Development of the Dietary Guidelines for Americans, 2025–2030

AGENCY: Department of Health and Human Services (HHS), Office of the Secretary, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion; Department of Agriculture (USDA), Food, Nutrition, and Consumer Services.

ACTION: Notice.

SUMMARY: The Departments of Health and Human Services and Agriculture solicit written comments on the scientific questions to be examined in the review of evidence supporting the development of the *Dietary Guidelines for Americans, 2025–2030.*

DATES: The scientific questions are available for review and public comment. Electronic or written/paper comments will be accepted through midnight Eastern Time on May 16, 2022.

ADDRESSES: The scientific questions are available on the internet at *www.DietaryGuidelines.gov.* Comments and attachments submitted electronically or by paper will be posted to the *www.regulations.gov* docket. You may submit comments as follows:

- *Electronic submissions:* Follow the instructions for submitting comments at *www.regulations.gov.*
- *Written/paper submissions:* Mail/courier to Janet M. de Jesus, MS, RD, Office of Disease Prevention and Health Promotion (ODPHP) Office of the Assistant Secretary for Health (OASH), HHS; 1101 Wootton Parkway, Suite 420; Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: Section 301 of the National Nutrition Monitoring and Related Research Act of 1990 (7 U.S.C. 5341) requires the Secretaries of HHS and USDA to publish the *Dietary Guidelines for Americans* (*Dietary Guidelines*) jointly at least every five years. The most recent edition of the Dietary Guidelines (2020–2025) provided guidance on the entire life span, from birth to older adulthood, including pregnancy and lactation. The *Dietary Guidelines for Americans, 2025–2030* will continue to address what to eat and drink across the entire lifespan to meet nutrient needs, promote health, and reduce the risk of chronic disease.

The Departments are identifying scientific questions to be considered in the review of evidence to support the development of the *Dietary Guidelines for Americans, 2025–2030.* Given the prevalence of chronic diseases in the United States, scientific questions will continue to examine the relationship between diet and health outcomes, and a special emphasis will be placed on questions that address food-based strategies that can be used to help individuals implement the *Dietary Guidelines* and prevent or manage overweight and obesity. In establishing this list of scientific questions, the Departments are considering the following criteria for prioritization: relevance to the *Dietary Guidelines,* importance to public health, potential impact to federal programs, avoiding duplication with other federal efforts, and research availability. The list of questions, more information on the criteria for prioritization, and background on the process for developing the questions is available at *www.dietaryguidelines.gov.*

- *Electronic or Written Public Comments:* Comments will be accepted through 11:59 p.m. Eastern Time May 16, 2022 at *www.regulations.gov.* Comments received by mail/courier will be considered if they are postmarked on or before May 16, 2022. Written comments via mail/courier will be uploaded into *www.regulations.gov* and are under the same limitations as for those submitted electronically to *www.regulations.gov:* 5,000 (with spaces) character limit for text box, and a maximum number of ten attached files and maximum size (10 MB) of each attached file. Please make note of copyright issues on your attachments. A link to the *www.regulations.gov* electronic filing system will also be available at *www.DietaryGuidelines.gov.*

HHS and USDA request comments on the list of scientific questions to be examined in the review of evidence supporting the development of the *Dietary Guidelines for Americans, 2025–2030.* Specifically, HHS and USDA request comments in support of or opposition to the proposed scientific questions. If a new scientific question is suggested, provide a brief summary of the topic, including information pertaining to the prioritization criteria listed above. It is requested that comments be limited to one page per topic. HHS and USDA will consider all relevant comments in finalizing the list of topics and questions to be examined in the development of the *Dietary Guidelines, 2025–2030.*

Contact Person for Additional Information: Janet de Jesus, MS, RD, Nutrition Advisor, telephone 240–453–8266, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, *DietaryGuidelines@hhs.gov.*

Dated: April 11, 2022.

Rachel L. Levine,

Assistant Secretary for Health, U.S. Public Health Service.

[FR Doc. 2022–08043 Filed 4–14–22; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Novel Synthetic NA Technology Development.

Date: May 9, 2022.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.