

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, PCNS@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 206031, drisapersen solution for injection, sponsored by BioMarin Pharmaceutical Inc., for the treatment of patients with Duchenne muscular dystrophy with mutations in the dystrophin gene that are amenable to treatment with exon 51 skipping as determined by genetic testing.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 9, 2015. Oral presentations from the public will

be scheduled between approximately 12:40 p.m. and 2:40 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 30, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 2, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 8, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015-26162 Filed 10-14-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Solicitation of Written Comments on Modifications of Healthy People 2020 Objectives

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

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services solicits written comments regarding new objectives proposed to be added to Healthy People 2020 since the fall 2014 public comment period, as well as written comments proposing new objectives to be included within existing Healthy People 2020 topic areas. Public participation helps shape Healthy People 2020, its framework, objectives, organization, and targets. Healthy People 2020 will provide opportunities for public input periodically throughout the decade to ensure that Healthy People 2020 reflects current public health priorities and public input. The updated set of Healthy People 2020 objectives will be incorporated on www.HealthyPeople.gov. This set will reflect further review and deliberation by the topic area workgroups, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

DATES: Written comments will be accepted until 5:00 p.m. ET on November 16, 2015.

ADDRESSES: Written comments will be accepted via an online public comment database at <http://www.healthypeople.gov/2020/about/history-development/Public-Comment>; by mail at the Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Attn: Public Comment, 1101 Wootton Parkway, Room LL-100, Rockville, MD 20852; fax—(240) 453-8281; or email—HP2020@hhs.gov.

FOR FURTHER INFORMATION CONTACT: Caitie Blood, MPH, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Room LL-100, Rockville, MD 20852, Caitlin.Blood@HHS.gov (email), (240) 453-8265 (telephone), (240) 453-8281 (fax).

SUPPLEMENTARY INFORMATION: For three decades, Healthy People has provided a comprehensive set of national 10-year health promotion and disease prevention objectives aimed at improving the health of all Americans. Healthy People 2020 objectives provide a framework by presenting a comprehensive picture of the nation's health at the beginning of the decade, establishing national goals and targets to be achieved by the year 2020, and monitoring progress over time. The U.S. Department of Health and Human Services is soliciting the submission of written comments regarding new objectives proposed to be added to Healthy People 2020 since the fall 2014 public comment period.

Healthy People 2020 is the product of an extensive collaborative process that relies on input from a diverse array of individuals and organizations, both within and outside the federal government, with a common interest in improving the nation's health. Public comments were a cornerstone of Healthy People 2020's development. During the first phase of planning for Healthy People 2020, HHS asked for the public's comments on the vision, mission, and implementation of Healthy People 2020. Those comments helped set the framework for Healthy People 2020. The public was also invited to submit comments on proposed Healthy People 2020 objectives, which helped shape the final set of Healthy People 2020 objectives.

The public is now invited to comment on new objectives proposed to be added to Healthy People 2020. These new objectives were developed by topic area workgroups led by various agencies within the federal government. They have been reviewed by the Federal Interagency Workgroup on Healthy People 2020 and are presented now for the public's review and comment. The public is also invited to suggest additional objectives for consideration that address critical public health issues within existing Healthy People 2020 topic areas. Any proposed new objective must meet all of the objective selection criteria (see below).

Written comments will be accepted at <http://www.healthypeople.gov/2020/about/history-development/Public-Comment> during a 30-day public comment period beginning in October 2015. The public will also be able to submit written comments via mail, fax, and email (see contact information above). Comments received in response to this notice will be reviewed and considered by the appropriate topic area workgroup, Federal Interagency Workgroup on Healthy People 2020, and other Healthy People 2020 stakeholders.

Objective Selection Criteria

The following nine criteria should be taken into consideration when commenting on the proposed new objectives or suggesting additional objectives.

1. The result to be achieved should be important and understandable to a broad audience and support the Healthy People 2020 goals.

2. Objectives should be prevention oriented and should address health improvements that can be achieved through population-based and individual actions, and systems-based, environmental, health-service, or policy interventions.

3. Objectives should drive actions that will work toward the achievement of the proposed targets (defined as quantitative values to be achieved by the year 2020).

4. Objectives should be useful and reflect issues of national importance. Federal agencies, states, localities, non-governmental organizations, and the public and private sectors should be able to use objectives to target efforts in schools, communities, work sites, health practices, and other environments.

5. Objectives should be measurable and should address a range of issues, such as: Behavior and health outcomes; availability of, access to, and content of behavioral and health service interventions; socio-environmental conditions; and community capacity—directed toward improving health outcomes and quality of life across the life span. (Community capacity is defined as the ability of a community to plan, implement, and evaluate health strategies.)

6. Continuity and comparability of measured phenomena from year to year are important, thus, when appropriate, retention of objectives from previous Healthy People iterations is encouraged. However, in instances where objectives and/or measures have proven ill-suited to the purpose or are inadequate, new improved objectives should be developed. Whether or not an objective has met its target in a previous Healthy People iteration should not be the sole basis for retaining or archiving an objective.

7. The objectives should be supported by the best available scientific evidence. The objective selection and review processes should be flexible enough to allow revisions to objectives in order to reflect major updates or new knowledge.

8. Objectives should address population disparities. These include populations categorized by race/ethnicity, socioeconomic status, gender, disability status, sexual orientation, and geographic location. For particular health issues, additional special populations should be addressed, based on an examination of the available evidence on vulnerability, health status, and disparate care.

9. Healthy People 2020, like past versions, is heavily data driven. Valid, reliable, nationally representative data and data systems should be used for Healthy People 2020 objectives. Each objective must have (1) a data source, or potential data source, identified, (2) baseline data and (3) assurance of at least one additional data point throughout the decade.

Dated: October 9, 2015.

Don Wright,

Deputy Assistant Secretary for Health, Office of Disease Prevention and Health Promotion.

[FR Doc. 2015-26244 Filed 10-14-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings 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 materials, 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 Institute on Drug Abuse Special Emphasis Panel—Harnessing Genome Editing Technologies to Functionally Validate Genetic Variants in Substance Use Disorders (R21/R33).

Date: November 6, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Jagadeesh S. Rao, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 02892, 301-443-9511, jrao@nida.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel—Phase II In-person Interview: NIDA Avant-Garde Award Program for HIV/AIDS Research (DP1).

Date: December 1, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301-402-6020, hiromi.ono@nih.gov.

Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)