

DATES: Electronic or written comments must be received by August 23, 2019.

ADDRESSES: You may submit comments, identified by CDC-2019-0016 and NIOSH-325, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC-2019-0016; NIOSH-325]. All relevant comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>. All information received in response to this notice will also be available for public examination and copying at the NIOSH Docket Office, 1150 Tusculum Avenue, Room 155, Cincinnati, OH 45226-1998.

FOR FURTHER INFORMATION CONTACT: Jeffrey H. Welsh, NIOSH Office of Mine Safety and Health Research, 315 E Montgomery Ave., Spokane, WA 99207. Phone: 412-386-4040 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background: The mining industry has been undergoing significant changes as companies look to adopt automation technologies to decrease costs and increase efficiency and, according to some companies, improve safety. These new technologies include automated mobile equipment, robotics, teleoperation, wireless communications and sensing systems, wearable sensors and computers, virtual and augmented reality, and data analytics. Surface iron ore mines in Western Australia are moving rapidly to adopt automation technologies, and they appear to be the closest in achieving completely autonomous mining. In U.S. mines, the adoption of automation technology is gaining momentum, with some of the first automation having been applied to processing facilities, drilling equipment, underground coal mine longwalls, and now pilot projects with automated haulage trucks and loaders.

Information Needs: To prepare for expanded use of automation technologies, NIOSH seeks to both proactively address worker health and safety challenges that may be associated with automation, as well as leverage new technologies to improve miner health and safety. To understand the

state of automation technologies, their implementation in the United States, and the health and safety concerns associated with the technology, NIOSH seeks public input on the following questions:

1. To what extent will automation and associated technologies be implemented in mining and in what timeframe?

2. What are the related health and safety concerns with automation and associated technologies in mining?

3. What gaps exist in occupational health and safety research related to automation and associated technologies?

While the above questions have priority, NIOSH also seeks public comment on the state of the technology and the health and safety concerns associated with the following specific topics related to automation:

4. What are the major safety concerns associated with humans working near or interacting with automated mining equipment? Have other organizations addressed the safety concerns associated with humans working near or interacting with automated mining equipment? If yes, please provide a description.

5. What research has been conducted, or approaches taken, to address the potential for human cognitive processing confusion, misunderstanding, and task or information overload associated with monitoring or controlling automated mining equipment or other monitoring systems (e.g., fleet management, environmental monitoring, safety systems, health care systems)?

6. What is the state of the art for display methodologies and technologies to provide mine personnel and equipment operators with information on operational status, location, and sensory and environmental feedback from automated mining equipment or systems?

7. What sensor technology improvements are needed to ensure the safety of humans working on or near automated equipment?

8. How are existing methods of big data analytics applied to automated mining equipment or systems? Are there health and safety benefits to these applications? If yes, please describe.

9. Are there any needed improvements to guidelines or industry standards for automated mining system safe design and operation practices? If yes, please describe.

10. Are there any needed improvements to training materials, training protocols, and operating procedures for system safety design

principles related to automated mining systems? If yes, please describe.

NIOSH is seeking feedback on the research areas identified above and on any additional knowledge gaps, ideas, innovations, or practice improvements not addressed by these research areas, as well as feedback on how the research areas should be prioritized. NIOSH is especially interested in any creative and new ideas as they relate to protecting the health and safety of miners today and in the future. When possible, NIOSH asks that commenters provide data and citations of relevant research to justify their comments. NIOSH is also seeking key scientific articles addressing worker safety and health related to mining automation that could inform our research activities.

References

- DoD [2000]. Standard practice for system safety. U.S. Department of Defense, MIL-STD-882D.
- Endsley MR [1995]. Toward a theory of situational awareness in dynamic systems. *Hum Factors* 37(1):32-64.
- USBM [1988]. Human factors in mining. By Sanders MS, Peay JM. Pittsburgh, PA: U.S. Department of the Interior, Bureau of Mines, IC 9182.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2019-13351 Filed 6-21-19; 8:45 am]

BILLING CODE 4163-19-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-4609]

Issuance of Priority Review Voucher; Rare Pediatric Disease Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of a priority review voucher to the sponsor of a rare pediatric disease product application. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the award of the priority review voucher. FDA has determined that ZOLGENSMA (onasemnogene abeparvec-xioi),

manufactured by AveXis, Inc., meets the criteria for a priority review voucher.

FOR FURTHER INFORMATION CONTACT:

Shruti Modi, 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: FDA is announcing the issuance of a priority review voucher to the sponsor of an approved rare pediatric disease product application. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria upon approval of those applications. FDA has determined that ZOLGENSMA (onasemnogene abeparvovec-xioi), manufactured by AveXis, Inc., meets the criteria for a priority review voucher. ZOLGENSMA (onasemnogene abeparvovec-xioi) is indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy with biallelic mutations in the survival motor neuron 1 gene.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to <https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm>. For further information about ZOLGENSMA (onasemnogene abeparvovec-xioi), go to the Center for Biologics Evaluation and Research Cellular and Gene Therapy Products website at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products>.

Dated: June 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2779]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this meeting.

DATES: The meeting will be held on August 7, 2019, from 8:30 a.m. to 4:30 p.m.

ADDRESSES: 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: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2019-N-2779. The docket will close on August 6, 2019. Submit either electronic or written comments on this public meeting by August 6, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 6, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 6, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before July 24, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments 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 FDA-2019-N-2779 for "Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see the **ADDRESSES** section), 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." FDA 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