

application. FDA is issuing this order because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions and sentence.

DATES: The order is applicable July 14, 2023.

FOR FURTHER INFORMATION CONTACT:

Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240-402-8743, debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on January 25, 2023 (88 FR 4826), Mark Moffett was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262). The debarment was based on FDA's finding, under section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)), that Mr. Moffett had been convicted of a felony under Federal law for conduct relating to the regulation of any drug product.

Mr. Moffett appealed the judgment of the District Court, and on November 18, 2022, the U.S. Court of Appeals for the First Circuit issued a judgment vacating Mr. Moffett's convictions as to all counts. On January 26, 2023, Mr. Moffett petitioned FDA for withdrawal of his debarment, citing section 306(d)(3)(B)(i) of the FD&C Act. Pursuant to section 306(d)(3)(B)(i) of the FD&C Act, "If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) . . . is reversed, the Secretary shall withdraw the order of debarment."

FDA has concluded that because the U.S. Court of Appeals for the First Circuit vacated Mr. Moffett's convictions, the order of debarment must be withdrawn. Accordingly, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(d)(3)(B)(i) of the FD&C Act, under authority delegated to the Assistant Commissioner, is issuing this order withdrawing the order that permanently debarred Mark Moffett from providing services in any capacity to a person with an approved or pending drug product application.

Dated: July 10, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-14929 Filed 7-13-23; 8:45 am]

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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: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) scheduled a public meeting to be held Thursday, August 10, 2023, and Friday, August 11, 2023. Information about ACHDNC and the agenda for this meeting can be found on ACHDNC's website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Thursday, August 10, 2023, from 10:00 a.m. to 3:00 p.m. Eastern Time (ET) and Friday, August 11, 2023, from 10:00 a.m. to 2:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Persons wishing to register to attend the meeting can do so via this link: <https://achdncmeetings.org/registration/>. Registration closes at 12:00 p.m. ET on August 9, 2023. 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 1 year from the Secretary's adoption of the condition for screening.

During the August 10-11, 2023, 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:

- A presentation on health equity and newborn screening;
- An update on the Duchenne muscular dystrophy condition nomination and a potential vote on whether to move it forward to full evidence-based review, which, depending on the strength of the evidence, could lead to a future recommendation to add this condition to the RUSP;
- A presentation, discussion, and vote on an ACHDNC expedited review process for resubmitted condition nomination packages; and
- A potential presentation and vote on whether to consider Krabbe disease through the ACHDNC expedited review process described above.

The agenda for this meeting includes a potential vote on whether to recommend a nominated condition (Duchenne muscular dystrophy) to full evidence-based review. In addition, as noted in the agenda items, the Committee may hold a vote on whether to recommend a nominated condition (Krabbe disease) be considered through the ACHDNC expedited review process described above. Both votes may lead to a recommendation to add or not add these 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 an opportunity to provide comments on any or all of the above agenda items. 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 are tentatively scheduled to provide their statements on Thursday, August 10, 2023. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Wednesday, July 26, 2023. Written comments will be shared with the Committee, so that they have an opportunity to consider them prior to the meeting.

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.

Amy P. McNulty,

Deputy Director, Executive Secretariat.

[FR Doc. 2023-14957 Filed 7-13-23; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 1009 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 Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Collaborative and Innovative Acceleration Awards.

Date: September 27, 2023.

Time: 11:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Center for Advancing Translational Sciences, 6701 Democracy Boulevard, Room 1073, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific

Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1073, Bethesda, MD 20892, 301-435-0810, lourdes.ponce@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: July 11, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-14956 Filed 7-13-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 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 Eye Institute Special Emphasis Panel; Pathway to Independence Award (K99).

Date: August 10, 2023.

Time: 12:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Ashley Fortress, Ph.D., Designated Federal Official, Division of Extramural Activities, National Eye Institute, National Institutes of Health, 6700 B Rockledge Drive, Bethesda, MD 20817, (301) 451-2020, ashley.fortress@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 11, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-14975 Filed 7-13-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Eye Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Eye Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Eye Institute.

Date: July 31–August 1, 2023.

Time: July 31, 2023, 9:00 a.m. to 6:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Claude D. Pepper Building, 6C, Rooms A and B, 31 Center Drive Bethesda, MD 20892 (Hybrid Meeting).

Time: August 01, 2023, 9:15 a.m. to 1:30 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: Claude D. Pepper Building, 6C, Rooms A and B, 31 Center Drive, Bethesda, MD 20892, (Hybrid Meeting).

Contact Person: David M Schneeweis, Ph.D., Acting Scientific Director, National Eye Institute, National Institutes of Health, Building 31, Room 6A22, Bethesda, MD 20892, 301-451-6763, David.schneeweis@nih.gov.

Information is also available on the Institute's/Center's home page: <https://www.nei.nih.gov/about/advisory-committees>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: July 11, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-14979 Filed 7-13-23; 8:45 am]

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