

NINLARO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NINLARO is 2,538 days. Of this time, 2,404 days occurred during the testing phase of the regulatory review period, while 134 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 10, 2008. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 10, 2008.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* July 10, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for NINLARO (NDA 208462) was initially submitted on July 10, 2015.

3. *The date the application was approved:* November 20, 2015. FDA has verified the applicant's claim that NDA 208462 was approved on November 20, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 837 or 157 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must 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: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00994 Filed 1–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

DATES: Thursday, February 8, 2018, from 9:30 a.m. to 5:00 p.m. and Friday, February 9, 2018, from 9:30 a.m. to 3:00 p.m. ET (meeting times are tentative).

ADDRESSES: The address for the meeting is 5600 Fishers Lane, 5th Floor Pavilion, Rockville, MD 20857. Participants may also access the meeting through Webcast. Advanced registration is required. Please register online at <http://www.achdncmeetings.org/> by 12:00 p.m. ET on February 5, 2018. Instructions on how to access the meeting via Webcast will be provided upon registration.

Please note that the 5600 Fishers Lane building requires security screening on entry. Visitors must provide a driver's license, passport, or other form of government-issued photo identification or they cannot enter the facility. Non-US Citizens planning to attend in person will need to provide additional information to HRSA by January 24, 2018, 12:00 p.m. Eastern Time. Please see contact information below.

FOR FURTHER INFORMATION CONTACT:

Anyone requesting information regarding the ACHDNC should contact Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three

ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301–443–3999; or (3) send an email to: AFerrero@hrsa.gov.

SUPPLEMENTARY INFORMATION: The ACHDNC provides advice to the Secretary of HHS 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. In addition, ACHDNC's recommendations regarding inclusion of additional conditions and inherited disorders for screening which have been adopted by the Secretary are then included in the Recommended Uniform Screening Panel (RUSP). Conditions listed on the RUSP constitute part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13. Under this provision, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible 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. Information about the ACHDNC is available on the following website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

The meeting agenda will include a final evidence-based review report on the spinal muscular atrophy (SMA) condition nomination for possible inclusion on the RUSP. Following this report, the ACHDNC expects to vote on whether to recommend to the Secretary adding SMA to the RUSP. ACHDNC members will also hear presentations on states' activities to achieve newborn screening timeliness goals. An overview of cutoff determinations and risk assessment methods used for dried bloodspot newborn screening will also be given. The Committee expects to vote on whether to support a guidance document on cutoff determinations and risk assessment methods. Finally, the ACHDNC members will hear updates from the Laboratory Standards and Procedures workgroup; the Follow-up and Treatment workgroup, including a presentation of the final draft of a report on Quality Measures in Newborn Screening; and the Education and Training workgroup, including a presentation of the final draft of a

Communication Guide for relaying Newborn Screening results.

HRSA will post the agenda two days prior to the meeting on the Committee's website: <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>. Please note that agenda items are subject to changes as priorities dictate.

Members of the public will have the opportunity to provide comments and may submit written comments in advance of the meeting. All comments are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on January 31, 2018, at <http://www.achdncmeetings.org/>. To accommodate all individuals who have registered and requested time for oral comments, the allocated time for comments may be limited. The ACHDNC may ask individuals associated with groups, or individuals who plan to provide comments on similar topics, to combine their comments and present them through a single representative. Audiovisual presentations are not permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.*, parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Ann Ferrero using the address and phone number above at least 10 days prior to the meeting.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-00978 Filed 1-19-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; Partnerships for the Development of Vaccines and Immunophylactics Targeting Multiple Antibiotic-Resistant Bacteria (R01).

Date: February 12–13, 2018.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Kelly Y. Poe, Ph.D., Scientific Review Program, Division of Extramural Activities, Room 3F40B, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5036, poeky@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: January 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-00959 Filed 1-19-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 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 Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Clinical Research, Clinical Trials, and Clinical Trials Planning Grants.

Date: February 12, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Rm. 676, Bethesda, MD 20892–4878, 301–594–4861, mooremar@nidcr.nih.gov.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR DSR Member Conflict SEP.

Date: February 14, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Rm. 676, Bethesda, MD 20892–4878, 301–594–4861, mooremar@nidcr.nih.gov.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel.

Date: February 28, 2018.

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: Nisan Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Branch, NIDCR, NIH, 6701 Democracy Boulevard, Suite 668, Bethesda, MD 20892, 301–451–2405, nisan_bhattacharyya@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: January 16, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-00962 Filed 1-19-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

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

The meeting will be open to the public as indicated below, with