CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, ELUCIREM (gadopiclenol) indicated in adult and pediatric patients aged 2 years and older for use with magnetic resonance imaging to detect and visualize lesions with abnormal vascularity in: the central nervous system (brain, spine, and associated tissues), the body (head and neck, thorax, abdomen, pelvis and musculoskeletal system). Subsequent to this approval, the USPTO received a patent term restoration application for ELUCIREM (U.S. Patent No. 8,114,863) from Guerbet LLC and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 19, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ELUCIREM 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 ELUCIREM is 2,443 days. Of this time, 2,199 days occurred during the testing phase of the regulatory review period, while 244 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: January 15, 2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 15, 2016.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act: January 21, 2022. FDA has verified the applicant's claim that the new drug application (NDA) for ELUCIREM (NDA 216986) was initially submitted on January 21, 2022.

3. The date the application was approved: September 21, 2022. FDA has verified the applicant's claim that NDA 216986 was approved on September 21, 2022.

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 application for patent extension, this applicant seeks 1,344 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: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21929 Filed 9–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4392]

Live Biotherapeutic Products To Prevent Necrotizing Enterocolitis in Very Low Birth Weight Infants; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency), the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), the National Institute of Allergy and Infectious Diseases (NIAID), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) (collectively, we) are

announcing a public workshop entitled ''Live Biotherapeutic Products to Prevent Necrotizing Enterocolitis in Very Low Birth Weight Infants.'' The purpose of the public workshop is to exchange information with the medical and scientific community about the regulatory and scientific issues associated with use of live biotherapeutic products to prevent necrotizing enterocolitis (NEC) in very low birth weight (VLBW) infants.

DATES: The public workshop will be held on October 25, 2024, from 9 a.m. to 4 p.m. Eastern Time. Either electronic or written comments on this public workshop must be submitted by November 25, 2024. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the NIH, National Institute of Allergy and Infectious Diseases Building, 5601 Fishers Lane, Rockville, MD 20892. Entrance for public workshop participants (non-NIH employees) is through the NIAID Building front lobby entrance where routine security check procedures will be performed. For parking and security information, please refer to *https://www.niaid.nih.gov/about/visitor-information.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 25, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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 Docket No. FDA–2024–N–4392 for ''Live Biotherapeutic Products to Prevent Necrotizing Enterocolitis in Very Low Birth Weight Infants.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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, 240–402–7500.

- 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.'' The Agency 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 copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Ryan Ranallo, National Institute of Allergy and Infectious Diseases, Division of Microbiology and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20852, 240–479–1958, *ryan.ranallo@nih.gov;* or Peter Weina, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 202–740–8687.

SUPPLEMENTARY INFORMATION:

I. Background

Necrotizing enterocolitis (NEC) in very low birth weight infants (VLBW) remains a significant public health problem. FDA has not approved any products, including live biotherapeutic products, for the prevention of NEC. Various products marketed as probiotics have been used in efforts to prevent this serious and life-threatening outcome; however, substantial evidence of effectiveness has not been demonstrated and serious adverse outcomes, including death, have been reported following use of probiotics in preterm infants.

II. Topics for Discussion at the Public Workshop

This public workshop is convened to: (1) advance a shared understanding of the epidemiology of NEC; (2) review current feeding practices; (3) discuss limitations of NEC case definitions; (4) review dynamics of the microbiome and NEC pathogenesis; (5) discuss the state of the evidence for probiotic use to prevent NEC; (6) review safety signals with probiotics; (7) explore clinical trial considerations; and (8) discuss challenges and opportunities in advancing development of Live Biotherapeutic Products as safe and effective products for the prevention of NEC in VLBW infants.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website for registration information: *https://cvent.me/9NerMP.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in-person must register by October 11, 2024, 11:59 p.m. Eastern Time. Early registration is recommended because in-person seating is limited; therefore, we may limit the number of participants from each organization.

If you need special accommodations due to a disability, please contact Ms. Christina McCormick, *christina.mccormick@nih.gov,* no later than October 15, 2024.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the public comment session. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants by October 18, 2024. All requests to make oral presentations must be received by the close of registration on October 11, 2024, at 11:59 p.m. Eastern Time. If selected for presentation, any presentation materials must be emailed to Ryan Ranallo (*ryan.ranallo@nih.gov*) no later than October 22, 2024. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast on *https://videocast.nih.gov/.*

Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Recording: Please be advised that as soon as possible after a recording of the public workshop is available, it will be accessible at *https://videocast.nih.gov/PastEvents* and available until October 25, 2025.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Dated: September 20, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21928 Filed 9–24–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session can also be accessed at the following NIH Videocast URL link *https://videocast.nih.gov.*

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 Advisory Council for Complementary and Integrative Health.

Date: January 24, 2025.

Closed: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, DEM 2, 6707 Democracy Boulevard, Bethesda, MD 20892, Virtual Meeting.

Open: 12:30 p.m. to 4:00 p.m.

Agenda: Reports and Updates about Recent and Ongoing NCCIH Led or Involved Activities by NCCIH staff and its Director.

Place: National Institutes of Health, DEM 2, 6707 Democracy Boulevard, Bethesda, MD 20892, Virtual Meeting.

Contact Person: Martina Schmidt, Ph.D., Director, Division of Extramural Activities, National Center for Complementary & Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, (301) 594–3456, *schmidma@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should be less than 700 words in length, and should include the name, email address, telephone number and when applicable, the business or professional affiliation of the interested person. *Any member of the public may submit written comments no later than January 10th, 2024 (14 days before the council meeting).*

Information is also available on the Institute's/Center's home page: *https://nccih.nih.gov/about/naccih,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: September 19, 2024.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–21858 Filed 9–24–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 1009 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 on Drug Abuse Special Emphasis Panel; NIDA–K Alternate SEP.

Date: November 4, 2024.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marisa Srivareerat, Ph.D., Scientific Review Officer, Scientific Review Branch, Office of Extramural Policy, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 435–1258, *marisa.srivareerat@nih.gov.*