committee meeting link, or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committees will discuss supplemental new drug application (sNDA) 205422 s009, efficacy supplement for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., and Lundbeck, Inc., for the proposed treatment of agitation associated with Alzheimer's dementia.

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 website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before April 3, 2023, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Eastern Time. 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 April 6, 2023. 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 April 7, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

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 Joyce Frimpong (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://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: March 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06577 Filed 3–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1278 and FDA–2020–E–1279]

Determination of Regulatory Review Period for Purposes of Patent Extension; M6–C Artificial Cervical Disc

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for M6–C ARTIFICIAL CERVICAL DISC and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by May 30, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by September 26, 2023. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: 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 May 30, 2023. 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 Nos. FDA–2020–E–1278 and FDA–2020–E–1279 for ''Determination of Regulatory

Review Period for Purposes of Patent Extension; M6–C ARTIFICIAL CERVICAL DISC.'' 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 § 10.20 (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: 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 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 medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device M6–C ARTIFICIAL CERVICAL DISC. M6–C ARTIFICIAL CERVICAL DISC is indicated for reconstruction of the disc following single level discectomy in skeletally mature patients with intractable degenerative cervical radiculopathy with or without spinal cord compression at one level from C3 to C7. Subsequent to this approval, the USPTO received a patent term restoration application for M6–C ARTIFICIAL CERVICAL DISC (U.S. Patent No. 8,377,138) from Spinal Kinetics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 14, 2020, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of M6–C ARTIFICIAL CERVICAL DISC 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 M6–C ARTIFICIAL CERVICAL DISC is 4,081 days. Of this time, 3,617 days occurred during the testing phase of the regulatory review period, while 464 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* December 7, 2007. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective on May 12, 2010. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on December 7, 2007, which represents the IDE effective date.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* October 31, 2017. FDA has verified the applicant's claim that the premarket approval application (PMA) for M6–C ARTIFICIAL CERVICAL DISC (PMA 170036) was initially submitted October 31, 2017.

3. *The date the application was approved:* February 6, 2019. FDA has verified the applicant's claim that PMA 170036 was approved on February 6, 2019.

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 715 days or 1,321 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: March 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–06580 Filed 3–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Exemption of the Advanced Research Projects Agency for Health (ARPA–H) From Policies and Requirements of the National Institutes of Health (NIH)

AGENCY: Advanced Research Projects Agency for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of the U.S. Department of Health and Human Services (HHS) has statutory authority to exempt the Advanced Research Projects Agency for Health (ARPA–H) from certain policies and requirements of the National Institutes of Health (NIH) as necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals. Pursuant to such authority, and for the reasons stated herein, the Secretary is giving notice that he intends to exempt ARPA–H from all NIH policies and requirements subject to the limitations and condition stated herein.

FOR FURTHER INFORMATION CONTACT: Thomas Libert, 240–731–3874, *tom.libert@arpa-h.gov.*

SUPPLEMENTARY INFORMATION: This notice follows 87 FR 32174, published on May 24, 2022. The Consolidated Appropriations Act, 2023 (Public Law 117–328, enacted on December 29, 2022) includes authorizing language for ARPA–H. Notably, section 499A of the Public Health Service Act (PHSA), as added by section 2331(a) of the Consolidated Appropriations Act, 2023, establishes ARPA–H within NIH and provides that the Director, ARPA–H, shall report to the Secretary of HHS.

Subparagraph (A) of section 499A(a)(3) provides that the Secretary may exempt ARPA–H from NIH policies and requirements that are in effect on the day before the enactment of section 499A as necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals, except as otherwise provided for in section 499A and subject to the requirements of subparagraph (B). Subparagraph (B) of section 499A(a)(3) provides that not later than 90 days after the date of enactment of section 499A, the Secretary shall publish a notice in the **Federal Register** describing the specific NIH policies and requirements from which the Secretary intends to exempt ARPA–H, including a rationale for such exemptions.

Pursuant to section 499A(a)(3) of the PHSA, notice is hereby given that I intend to exempt ARPA–H from all policies and requirements of the NIH that were in effect on the day before the enactment of section 499A, that is, on December 28, 2022.

The exemption is necessary and appropriate to ensure ARPA–H can most effectively achieve its statutorily specified goals and consistent with prior actions for the following reasons:

- The mission of ARPA–H is complementary to NIH, but its business model is distinct and separate. To succeed at its mission to realize transformative health solutions, ARPA–H must establish a unique culture and distinct and separate business and operations processes, including its own policies and requirements.
- On April 15, 2022, I transferred ARPA–H to NIH as authorized by title II of division H of the Consolidated Appropriations Act, 2022 (Pub. L. 117–103, enacted on March 15, 2022) and delegated to the Director, NIH, certain authorities for the purpose of carrying out ARPA–H (87 FR 23526). As a condition of the delegation, I specified that NIH may not subject ARPA–H to NIH policies.
- As noted, section 499A of the PHSA establishes ARPA–H within NIH and provides that the Director, ARPA–H, shall report to the Secretary. In the Joint Explanatory Statement (168 Cong. Rec. S8895, 2022), Congress signaled its intent for ARPA–H to establish its own culture, procedures, and policies:

> The agreement strongly encourages HHS to collaborate with the Defense Advanced Research Projects Agency (DARPA) to develop the foundational policies, procedures, and staff training for ARPA–H employees. The agreement believes ARPA–H will require a very different culture and mission than NIH's other 27 Institutes and Centers.

ARPA–H shall continue to be subject to all policies and requirements of HHS. All major policy, programmatic, and operational decisions proposed by ARPA–H shall continue to come to the Secretary for approval.

The exemption is subject to the following condition:

- Where ARPA–H identifies a need to develop a policy or requirement to fulfill its mission, it shall rely upon NIH policies and requirements until such time as ARPA–H develops its own policies and requirements as appropriate.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023–06620 Filed 3–29–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Oncology.

Date: April 27, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nywana Sizemore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6189, MSC 7804, Bethesda, MD 20892, 301–408–9916, *sizemoren@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)