an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological 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 biological 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 biologic product AJOVY (fremanezumab-vfrm). AJOVY is indicated for the preventive treatment of migraine in adults. Subsequent to this approval, the USPTO received a patent term restoration application for AJOVY (U.S. Patent No. 8,007,794) from Teva Pharmaceuticals International GmbH, 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 human biological product had undergone a regulatory review period and that the approval of AJOVY 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 AJOVY is 3,216 days. Of this time, 2,882 days occurred during the testing phase of the regulatory review period, while 334 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 (21 U.S.C. 355(i)) became effective:* November 26, 2009. The applicant claims November 19, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 26, 2009, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* October 16, 2017. FDA has verified the applicant's claim that the biologics license application (BLA) for AJOVY (BLA 761089) was initially submitted on October 16, 2017.

3. *The date the application was approved:* September 14, 2018. FDA has verified the applicant's claim that BLA 761089 was approved on September 14, 2018.

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 1,454 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: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14652 Filed 7–8–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Neurodevelopmental and Neurological Disorders.

Date: August 3, 2021.

Time: 10:00 a.m. to 1:00 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: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Eye Disease and Infections.

Date: August 5, 2021.

Time: 11:00 a.m. to 4:00 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: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205, MSC 7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cognitive and Neuropathological Signatures of Alzheimer's Disease, Brain Injury and Aging.

Date: August 5, 2021.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Samuel C. Edwards, Ph.D., Chief, BDCN IRG, Center for Scientific Review, National Institutes of Health, 6701

Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@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)

Dated: July 2, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–14617 Filed 7–8–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 30-Day Comment Request: Generic Clearance To Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, (NIMH)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Andrew Hooper, NIMH Project Clearance Liaison, Science Policy and Evaluation Branch, Office of Science Policy, Planning and Communications, NIMH, Neuroscience Center, 6001 Executive Boulevard, MSC 9667, Bethesda, Maryland 20892, call (301) 480–8433, or email your request, including your mailing address, to *nimhprapubliccomments@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on May 5, 2021, pages 23974–23975 (Vol. 86, No. 85) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Mental Health (NIMH), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: Generic Clearance to Collect Stakeholder Feedback on the Research Domain Criteria (RDoC) Initiative, 0925–0756, EXTENSION, exp., date 07/31/2021, National Institute of Mental Health (NIMH), National Institutes of Health (NIH).

Need and Use of Information Collection: This request serves as notice that the National Institute of Mental Health (NIMH) plans to collect stakeholder feedback to assess the strengths and weaknesses of the Research Domain Criteria (RDoC) initiative. NIMH launched RDoC in 2009 to implement Strategy 1.4 of the 2008 NIMH Strategic Plan: ''Develop new ways of classifying disorders based on dimensions of observable behaviors and brain functions.'' Rather than beginning with a syndrome and then working ''down'' to clarify mechanisms, the aim of RDoC is to guide research that begins with disruptions in neurobiological and behavioral mechanisms, and then works across systems to clarify connections among such disruptions and clinical symptoms. NIMH has developed social media platforms and tools for the RDoC initiative, including a dedicated RDoC twitter account (*https://twitter.com/nimh_rdoc*), the RDoC website, which also houses the RDoC matrix (*https://www.nimh.nih.gov/research-priorities/rdoc/index.shtml*), and several educational and training resources (including webinars) to educate the field and interface with scientists who may have questions about RDoC (*https://www.nimh.nih.gov/research-priorities/rdoc/rdoc-educational-and-training-resources.shtml*). The evaluation approach will be conducted using surveys centered around current content (*i.e.,* website, twitter, and webinars), as well as open ended surveys that will cover the scientific content of RDoC. The information collected will be used by NIMH staff to determine success of the RDoC initiative, develop future directions and endeavors, and to help guide programmatic priorities for RDoC and the Institute.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 490.

ESTIMATED ANNUALIZED BURDEN HOURS

Instrument type	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Workshops	50	1	8	400
Interviews	10	1	30/60	5
Surveys	100	1	30/60	50
Focus Groups	10	1	1	10
Assessment Forms	100	1	15/60	25
Total	270	270	.....	490