

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, FASENRA (benralizumab). FASENRA is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older and with an eosinophilic phenotype. Subsequent to this approval, the USPTO received patent term restoration applications for FASENRA (U.S. Patent Nos. 7,179,464; 7,718,175; and 8,101,185) from Kyowa Hakko Kirin Co., Ltd., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 18, 2018, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of FASENRA 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 FASENRA is 4,127 days. Of this time, 3,763 days occurred during the testing phase of the regulatory review period, while 364 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:* July 30, 2006. The applicant claims July 29, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 30, 2006, 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):* November 16, 2016. FDA has verified the applicant's claim that the biologics license application (BLA) for FASENRA (BLA 761070) was initially submitted on November 16, 2016.

3. *The date the application was approved:* November 14, 2017. FDA has verified the applicant's claim that BLA 761070 was approved on November 14, 2017.

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 5 years, or 1,552 days or 1,244 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: February 27, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-04363 Filed 3-3-20; 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; Member Conflict: Hypertension and Microcirculation.

*Date:* March 23, 2020.

*Time:* 2:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Larry Pinkus, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4132, MSC 7802, Bethesda, MD 20892, (301) 435-1214, [pinkusl@csr.nih.gov](mailto:pinkusl@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroimmunology, Neuroinflammation, Infection, and Brain Cancer.

*Date:* March 24, 2020.

*Time:* 11:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*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](mailto:edwardss@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR19-385: Environmental Risks for Psychiatric Disorder: Biological Basis of Pathophysiology.

*Date:* March 24, 2020.

*Time:* 2:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Julius Cinque, MS, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7846, Bethesda, MD 20892, (301) 435-1252, [cinquej@csr.nih.gov](mailto:cinquej@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Motivated Behavior, Alcohol and Heavy Metals.

*Date:* March 25, 2020.

*Time:* 1:00 a.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, (301) 435-1119, [selmanom@csr.nih.gov](mailto:selmanom@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences.

*Date:* March 25, 2020.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

*Contact Person:* Eugene Carstee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7818, Bethesda, MD 20892, (301) 408-9756, [carstee@csr.nih.gov](mailto:carstee@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Drug Discovery and Clinical Field Studies.

*Date:* March 25, 2020.

*Time:* 10:00 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:* Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, (301) 435-2306, [boundst@csr.nih.gov](mailto:boundst@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Leveraging Health Information Technology (Health IT) to Address Minority Health and Health Disparities.

*Date:* March 25, 2020.

*Time:* 11:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Delia Olufokunbi Sam, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3158, MSC 7770, Bethesda, MD 20892, (301) 435-0684, [olufokunbisamd@csr.nih.gov](mailto:olufokunbisamd@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Toxicology and Digestive, Kidney and Urological Systems AREA/REAP Review.

*Date:* March 25, 2020.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Aiping Zhao, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2188, MSC 7818, Bethesda, MD 20892-7818, (301) 435-0682, [zhaoa2@csr.nih.gov](mailto:zhaoa2@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Cognitive Processing and Neuropsychiatric Disorders.

*Date:* March 25, 2020.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Jenny Raye Browning, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 402-8197, [jenny.browning@nih.gov](mailto:jenny.browning@nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Topics in Clinical Field Studies.

*Date:* March 25, 2020.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

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

*Contact Person:* Neerja Kaushik-Basu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3198, MSC 7808, Bethesda, MD 20892, (301) 435-2306, [kaushikbasun@csr.nih.gov](mailto:kaushikbasun@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroscience and Bioengineering.

*Date:* March 25, 2020.

*Time:* 3:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Robert C Elliott, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3130, MSC 7850, Bethesda, MD 20892, (301) 435-3009, [elliott@csr.nih.gov](mailto:elliott@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: February 27, 2020.

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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 on Aging Special Emphasis Panel; Preventative Health Services Use.

*Date:* March 9, 2020.

*Time:* 12:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Kimberly Firth, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, (301) 402-7702, [firthkm@mail.nih.gov](mailto:firthkm@mail.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Conference Grants.

*Date:* March 13, 2020.

*Time:* 12:00 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Dario Dieguez, Jr., Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827-3101, [dario.dieguez@nih.gov](mailto:dario.dieguez@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

**Miguelina Perez,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020-04377 Filed 3-3-20; 8:45 am]

**BILLING CODE 4140-01-P**