

BIOPROSTHESIS MODEL 11000A and MODEL 11500A are indicated for the replacement of native or prosthetic aortic heart valves. Subsequent to this approval, the USPTO received patent term restoration applications for EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS MODEL 11000A and MODEL 11500A (U.S. Patent Nos. 7,972,376; 8,007,992; 8,357,387; and 9,029,418) from Edwards Lifesciences Corporation, and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 5, 2018, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS 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 EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS is 1,858 days. Of this time, 1,491 days occurred during the testing phase of the regulatory review period, while 367 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption for this device, under section 520(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(g)), became effective:* May 30, 2012. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) for human tests to begin, as required under section 520(g) of the FD&C Act, became effective May 30, 2012.

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):* June 28, 2016. FDA has verified the applicant's claim that the premarket approval application (PMA) for EDWARDS PERICARDIAL AORTIC BIOPROSTHESIS (PMA P150048) was initially submitted June 28, 2016.

3. *The date the application was approved:* June 29, 2017. FDA has verified the applicant's claim that PMA P150048 was approved on June 29, 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 572 days, 992 days, or 1,111 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 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 Environmental Health Sciences Special Emphasis Panel: Exploratory Research on RNA Modifications Environment and Disease (FRAMED).

Date: September 16, 2019.

Time: 8:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Hotel, Raleigh-Durham Airport, 4810 Page Creek Lane, Durham, NC 27703.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, 919/541-0670, worth@niehs.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 of Environmental Health Sciences Special Emphasis Panel: Investigator-Initiated Functional RNA Modifications Environment and Disease (FRAMED).

Date: September 16–17, 2019.

Time: 3:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Hotel, Raleigh-Durham Airport, 4810 Page Creek Lane, Durham, NC 27703.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, 919/541-0670, worth@niehs.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. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: September 5, 2019.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-19606 Filed 9-10-19; 8:45 am]

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