

IDE was determined substantially complete for clinical studies to have begun on September 17, 2010, 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)*: December 22, 2014. The applicant claims December 19, 2014, as the date the premarket approval application (PMA) for SAPIEN 3 TRANSCATHETER HEART VALVE (PMA P140031) was initially submitted. However, FDA records indicate that PMA P140031 was submitted on December 22, 2014.

3. *The date the application was approved*: June 17, 2015. FDA has verified the applicant's claim that PMA P140031 was approved on June 17, 2015.

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 250 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: January 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01655 Filed 1–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the National Center for Advancing Translational Sciences Special Emphasis Panel.

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 Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Collaborative Innovation Award Review.

Date: February 22–23, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy I, Room 1068, 6701 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: M. Lourdes Ponce, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy I, Room 1073 Bethesda, MD 20892, 301–435–0810, lourdes.ponce@nih.gov.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; Bench Testing.

Date: February 27, 2018.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy I, Room 1066, 6701 Democracy Blvd., Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Barbara J. Nelson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy I, Room 1080, Bethesda, MD 20892–4874, 301–435–0806, nelsonbj@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: January 25, 2018.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–01822 Filed 1–29–18; 8:45 am]

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; GEMSTAR.

Date: February 26, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, MIKHAILI@MAIL.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel; Primate Aging Database and Management.

Date: March 1, 2018.

Time: 11:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, Suite 2W233, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Anita H. Undale, Ph.D., MD, Scientific Review Branch, National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 240–747–7825, anita.undale@nih.gov.

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