

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug 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 drug 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 drug product JUBLIA (efinaconazole). JUBLIA is indicated for the topical treatment of onychomycosis of the toenails due to *Trichophyton rubrum* and *Trichophyton mentagrophytes*. Subsequent to this approval, the USPTO received a patent term restoration application for JUBLIA (U.S. Patent No. 7,214,506) from Kaken Pharmaceutical Co., Ltd., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated November 4, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of JUBLIA 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 JUBLIA is 2,521 days. Of this time, 1,840 days occurred during the testing phase of the regulatory review period, while 681 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 (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 14, 2007. FDA has verified the applicant's claim that the date the investigational new drug application (IND) became effective was on July 14, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section*

*505(b) of the FD&C Act:* July 26, 2012. FDA has verified the applicant's claim that the new drug application (NDA) for JUBLIA (NDA 203567) was initially submitted on July 26, 2012.

3. *The date the application was approved:* June 6, 2014. FDA has verified the applicant's claim that NDA 203567 was approved on June 6, 2014.

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 1,601 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 31, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-02522 Filed 2-7-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: 0937-0191-30D]

### Agency Information Collection Request. 30-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before March 12, 2018.

**ADDRESSES:** Submit your comments to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When requesting information, please include the document identifier 0937-0191-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Application packets for Real Property for Public Health Purposes.

*Type of Collection:* Revision.  
*OMB No.:* 0937-0191-30D—Office within OS—Office of Assistant Secretary for Administration, Program Support Center, Real Estate, Logistics and Operations Support, Federal Property Assistance Program.

*Abstract:* The Office of Assistant Secretary for Administration, Program Support Center Federal Property Assistance Program is requesting approval by OMB on a revision. Cited, 40 U.S.C. 550, as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which, (except for institutions which lease property to assist the homeless) have been held exempt from taxation under Section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health purposes. Title V of the McKinney-Vento Homeless Assistance Act (Title V) extended the Secretary's authority to

include homeless assistance purposes as a permissible use under public health. The Federal Asset and Transfer Act of 2016 (Pub. L. 114–287) streamlined the Title V process bifurcating the application process. Transfers are made to transferees at little or no cost.

We are requesting that the collection be valid for three years.

*Type of respondent:* State and local governments and non-profit institutions use these applications to apply for excess/surplus, underutilized/unutilized and off-site government real property. These applications are used to

determine if institutions/organizations are eligible to purchase, lease or use property under the provisions of the surplus real property program. Responds are intermittent—only when an eligible organization requests acquisition of identified Federal surplus real property.

#### ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Applications for surplus Federal real property .....	15	1	200	3,000
Total .....	15	1	200	3,000

**Terry S. Clark,**

*Office of the Secretary, Asst. Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 2018–02477 Filed 2–7–18; 8:45 am]

**BILLING CODE 4150–04–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 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 Center for Advancing Translational Sciences Special Emphasis Panel; R13 Conference Grants Review.

*Date:* March 6, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, Room 1037, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Rahat Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, 6701 Democracy Blvd., Rm. 1078, Bethesda, MD 20892, 301–594–7319, [khanr2@csr.nih.gov](mailto:khanr2@csr.nih.gov).

*Name of Committee:* National Center for Advancing Translational Sciences Special Emphasis Panel; TRND—Contract Review.

*Date:* March 7, 2018.

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

*Agenda:* To review and evaluate contract proposals.

*Place:* National Institutes of Health, One Democracy Plaza, Room 1037, 6701 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Rahat (Rani) Khan, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, 6701 Democracy Blvd., Rm. 1078, Bethesda, MD 20892, 301–894–7319, [khanr2@csr.nih.gov](mailto:khanr2@csr.nih.gov).

*Name of Committee:* National Center for Advancing Translational Sciences Special Emphasis Panel; Platform Delivery Technologies for Nucleic Acid Therapeutics.

*Date:* March 29, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, Room 1065, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Carol Lambert, Ph.D., Acting Director, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1076, Bethesda, MD 20892, 301–435–0814, [lambert@mail.nih.gov](mailto:lambert@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: February 1, 2018.

**David Clary,**

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

[FR Doc. 2018–02492 Filed 2–7–18; 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 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: Pain Mechanisms.

*Date:* March 1, 2018.

*Time:* 8:00 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:* John Bishop, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5182, MSC 7844, Bethesda, MD 20892, (301) 408–9664, [bishopj@csr.nih.gov](mailto:bishopj@csr.nih.gov).

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

*Date:* March 1, 2018.

*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, (Virtual Meeting).