

exclusion and an average of 2,160 hours to prepare an EA.

TABLE 5—ESTIMATED ANNUAL REPORTING BURDEN FOR ANIMAL DRUGS <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d) .....	70	10	700	3	2,100
25.40(a) and (c) .....	10	1	10	2,160	21,600
Total .....					23,700

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

#### *Estimated Annual Reporting Burden for Tobacco Products*

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. In 2015, FDA estimated it will receive approximately 5 premarket reviews of new tobacco PMTAs from 5 respondents, 509 reports intended to

demonstrate the substantial equivalence of a new tobacco product (SEs) from 509 respondents, 15 exemptions from substantial equivalence requirements applications (SE Exemptions) from 15 respondents, and 3 modified risk tobacco product applications (MRTPAs) from 3 respondents. FDA is not accepting claims for categorical exclusions at this time, and estimates that there will be 532 EAs from 532 respondents as required under §§ 25.40(a) and (c). Therefore, over the next 3 years, FDA estimates that

approximately 532 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or MRTPA. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

TABLE 6—ESTIMATED ANNUAL REPORTING BURDEN FOR TOBACCO PRODUCTS <sup>1</sup>

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.40(a) and (c) .....	532	1	532	80	42,560

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 18, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

[Document Identifier: HHS-OS-0990-0406 30D]

#### **Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of

Management and Budget (OMB) for review and approval. The ICR is for renewal of the approved information collection assigned OMB control number 0990-0406, scheduled to expire on April 30, 2016. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

**DATES:** Comments on the ICR must be received on or before April 25, 2016.

**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:** Information Collection Clearance staff, [Information.CollectionClearance@hhs.gov](mailto:Information.CollectionClearance@hhs.gov) or (202) 690-6162.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the OMB control number 0990-0406 for reference.

*Information Collection Request Title:* Evaluation of the National Partnership for Action to End Health Disparities

**Abstract:** Office of Minority Health (OMH) in the Office of the Assistant Secretary for Health (OASH), Office of the Secretary (OS) is requesting approval for an extension from the Office of Management and Budget (OMB) for a previously approved data collection activity for the Evaluation of the National Partnership for Action to End Health Disparities (NPA). The NPA was officially launched in April 2011 to mobilize a nationwide, comprehensive, community-driven, and sustained approach to combating health disparities and to move the nation toward achieving health equity. Using an approach that vests those at the front line with the responsibility of identifying and helping to shape core actions, new approaches and new partnerships are being established to help close the health gap in the United States.

OMH proposes to continue to conduct the evaluation of the NPA. The evaluation's goal is to determine the extent to which the NPA has contributed to the elimination of health disparities and attainment of health

equity in our nation. The evaluation will accomplish this goal by addressing the following questions: (1) To what extent has a multi-level structure been established to support actions that will contribute to the elimination of health disparities? (2) How are leaders in the public, private, nonprofit, and community sectors engaged in collaborative, efficient, and equitable

working partnerships to eliminate health disparities? (3) How many and what types of identifiable actions are being implemented at the community, state, tribal, regional, and national levels that relate directly to the five goals and 20 strategies in the *National Stakeholder Strategy (NSS)*? (4) How much is the work to end health disparities integrated into stakeholder

strategies and mainstream systems (e.g., health care quality improvement, public and community health improvement, economic and community planning and development) in and beyond the health sector? (5) What are the promising practices for implementing actions that contribute to ending health disparities?

#### TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden per response (minutes)	Total burden hours
RHEC co-chairs .....	RHEC co-chairs interview .....	20	1	85	28
RHEC Subcommittee chairs .....	RHEC Subcommittee chairs group interviews.	50	1	90	75
RHEC members .....	Survey of all RHEC members .....	350	1	20	117
Key NPA partner organizations .....	Survey of Key NPA partner organizations.	15	1	25	6
State Minority Health Office Directors or Coordinators and State Department of Health Representatives.	Survey of State Minority Health Office Directors or Coordinators and officials from State Departments of Health.	110	1	20	37
Total .....	.....	545	.....	.....	263

**Terry S. Clark,**

*Asst Information Collection Clearance Officer.*

[FR Doc. 2016-06592 Filed 3-23-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting 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 Conflicts: Cardiovascular Sciences.

*Date:* April 6, 2016.

*Time:* 11:30 a.m. to 3:30 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:* Sara Ahlgren, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, RM 4136, Bethesda, MD 20892, 301-435-0904, [sara.ahlgren@nih.gov](mailto:sara.ahlgren@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. 93.306, 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:* March 18, 2016.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-06618 Filed 3-23-16; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Heart, Lung, and Blood Institute Special Emphasis Panel—Basic Research in HIV-Related Heart, Lung, and Blood Diseases (R01) .

*Date:* April 19, 2016.

*Time:* 8:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA National, Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7182, Bethesda, MD 20892, [sunnarborgsw@nhlbi.nih.gov](mailto:sunnarborgsw@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel Basic Research in HIV-Related Heart, Lung, and Blood Diseases (R21).

*Date:* April 19, 2016.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

*Contact Person:* Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of