

received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993-0002, 301-796-1500.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled "Respiratory Syncytial Virus Infection: Developing Antiviral Drugs for Prophylaxis and Treatment." This draft guidance addresses FDA's current thinking regarding the overall drug development program for an indication for treatment and prevention of disease caused by RSV infection including nonclinical development, early phases of clinical development, and phase 3 trial designs. This draft guidance focuses primarily on pediatric antiviral drug development for RSV but also discusses drug development for other populations.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Respiratory Syncytial Virus Infection: Developing Antiviral Drugs for Prophylaxis and Treatment." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This

guidance is not subject to Executive Order 12866.

**II. The Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910-0014 and 0910-0001, respectively.

**III. Electronic Access**

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: October 5, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017-22051 Filed 10-11-17; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier OS-0990-new]

**Agency Information Collection Request; 60-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 December 11, 2017.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to [Sherrette.funn@hhs.gov](mailto:Sherrette.funn@hhs.gov), or call the Reports Clearance Officer.

**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: I Can Do It, You Can Do It! Program Evaluation.*

*Type of Collection:* New.

OMB No. 0990-NEW—Office within OS—Office of the President's Council on Fitness, Sports & Nutrition (OPCFNS), Office of the Assistant Secretary for Health.

*Abstract:* Initiated by the former HHS Office on Disability, supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the former Division of Nutrition Research Coordination at the National Institutes of Health, and adopted by OPCFNS in 2011, the *I Can Do It, You Can Do It!* health promotion program is designed to provide access and opportunities for children and adults with a wide range of physical and cognitive disabilities to lead healthy, active lives. Approximately 56 million children and adults living in the United States have some level of disability. Despite physical activity and good nutrition being the cornerstones of evidence-based health promotion interventions for reducing the risk of comorbidities (e.g., diabetes, heart disease, stroke), many people with a disability or caregivers who have a child with a disability experience substantial difficulty accessing these programs. The program partners with K-12 schools and school districts, colleges and universities, and other community-based entities that implement the program using a mentoring approach that has been well-documented in the research literature as efficacious in changing the attitudes, knowledge, and health behaviors of individuals with and without a disability.

The information collected for the *I Can Do It, You Can Do It!* Program Evaluation will allow the OPCFNS and partners to assess the impact of the program and gather critical information for improvement.

## ANNUALIZED BURDEN HOUR TABLE

Forms	Respondents	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Advocate Form .....	Site Coordinator .....	10	1	20/60	3
Advocate Annual Follow-Up Survey	Site Coordinator .....	10	1	20/60	3
End of Wave 1 Interview Script .....	Site Coordinator .....	10	1	1	10
End of Wave 1 Feedback Survey ...	Site Coordinator .....	10	1	45/60	8
End of Wave 2 Interview .....	Site Coordinator .....	10	1	1	10
End of Wave 2 Feedback Survey ...	Site Coordinator .....	10	1	20/60	3
Technical Assistance Assessment ..	Site Coordinator .....	10	1	25/60	4
Mentee Pre-Assessment .....	Mentee/Program Participant .....	700	1	20/60	233
Mentee Post-Assessment .....	Mentee/Program Participant .....	700	1	20/60	233
Mentor Feedback Survey .....	Mentor .....	700	1	15/60	175
Weekly Goal-Setting Guide .....	Mentor .....	700	10	10/60	1166
Mentee Focus Group Script .....	Mentee/Program Participant .....	60	1	1	60
Parent/Guardian Focus Group Script.	Mentee's Parent/Guardian .....	60	1	1	60
Total .....	.....	.....	22	.....	1968

**Terry S. Clark,**

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

[FR Doc. 2017-21983 Filed 10-11-17; 8:45 am]

**BILLING CODE 4150-35-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; 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 Alcohol Abuse and Alcoholism, Special Emphasis Panel; NIAAA Fellowship Review.

*Date:* November 2, 2017.

*Time:* 8:30 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, Terrace Conference Room, 5635 Fishers Lane, Bethesda, MD 20892.

*Contact Person:* Richard A. Rippe, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol

Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Room 2109, Rockville, MD 20852 301-443-8599, [ripper@mail.nih.gov](mailto:ripper@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 Alcohol Abuse and Alcoholism Special Emphasis Panel, SEP Review Member Conflict Applications.

*Date:* November 14, 2017.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

*Contact Person:* Anna Ghambaryan, M.D., Scientific Review Officer, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rockville, MD 20852, 301-443-4032, [anna.ghambaryan@nih.gov](mailto:anna.ghambaryan@nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS).

Dated: October 5, 2017.

**Melanie J. Pantoja,**

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

[FR Doc. 2017-21989 Filed 10-11-17; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive Patent License: DNA-Based Vaccine for Prevention of Zika Virus Infection

**AGENCY:** National Institutes of Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to PaxVax, Inc., located in Redwood City, California, to practice the inventions embodied in the patent applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before November 13, 2017 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Dr. Amy Petrik, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 2G, MSC9804, Rockville, MD 20852-9804, phone number 301-496-2644, or [petrika@mail.nih.gov](mailto:petrika@mail.nih.gov).