

professionals. In May 2011, FDA convened a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee to discuss the use of acetaminophen in children. Shortly before the meeting, the Consumer Healthcare Products Association (CHPA) proposed to voluntarily phase out all of the existing single-ingredient concentrated drop formulations of the OTC, pediatric, oral, liquid acetaminophen drug products and market only the 160 mg/5 mL. At the Advisory Committee meeting, FDA took note of CHPA's voluntary transition to a single concentration of pediatric oral liquid acetaminophen.

In response to CHPA's voluntary transition to a single concentration of OTC oral liquid acetaminophen products, FDA published a Drug Safety Communication on December 22, 2011, to inform the public of the 160 mg/5 mL concentration now marketed for children ages 2 to 3 years and to recommend that end users of the product read the Drug Facts label to identify the concentration of the oral liquid acetaminophen, dosage, and directions for use.

FDA issued the draft guidance on October 8, 2014 (79 FR 60854), to address ongoing concerns about the potential for acetaminophen overdose associated with these products and to encourage safer use. Comments on the draft guidance were considered while finalizing this guidance, which has been revised and clarified in some respects.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on addressing safety achieved through drug product design and labeling to minimize medication errors. 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.

## II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## III. Paperwork Reduction Act of 1995

This guidance refers to a previously approved collection of information found in FDA regulations. The collection of information is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information referenced in this guidance that pertain to the format and content requirements for OTC drug product labeling (§ 201.66) have been approved under OMB control number 0910–0340. The labeling requirements in § 201.326 are not subject to review by OMB because they do not constitute a “collection of information” under the PRA. Rather, the labeling statements are a “public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

## IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: July 30, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–19178 Filed 8–4–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Open Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (<http://videocast.nih.gov/>).

*Name of Committee:* National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

*Date:* November 4, 2015.

*Time:* 8:30 a.m. to 4:00 p.m.

*Agenda:* Strategic Discussion of NCI's Clinical and Translational Research Programs.

*Place:* National Institutes of Health, Building 31, C-Wing, 6th Floor, Room 10, 31 Center Drive, Bethesda, MD 20892.

*Contact Person:* Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 6W136, Rockville, MD 20850, 240–276–6173, [prindivs@mail.nih.gov](mailto:prindivs@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 31, 2015.

**David Clary,**

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

[FR Doc. 2015–19193 Filed 8–4–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30 Day Comment Request; Post-Award Reporting Requirements Including Research Performance Progress Report Collection (OD/OPERA)

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection

listed below. This proposed information collection was previously published in the **Federal Register** on March 16, 2015, Volume 80, No. 50, pages 13568–13569 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Direct Comments to OMB:** Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA\_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and

instruments, contact: Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or Email your request, including your address to:

*ProjectClearanceBranch@mail.nih.gov.*

**Proposed Collection:** Public Health Service (PHS) Post-award Reporting Requirements. Revision, OMB 0925–0002, Expiration Date 8/31/2015. Form numbers: PHS 2590, PHS 416–7, PHS 2271, PHS 3734, PHS 6031–1, and HHS 568.

**Need and Use of Information Collection:** The RPPR is now required to be used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR required the maintenance of dual reporting processes for a period of time. Continued use of the PHS Non-competing Continuation Progress Report (PHS 2590), exists for a small group of grantees. This collection also includes other PHS post-award reporting

requirements: PHS 416–7 NRSA Termination Notice, PHS 2271 Statement of Appointment, 6031–1 NRSA Annual Payback Activities Certification, HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant. The PHS 416–7, 2271, and 6031–1 are used by NRSA recipients to activate, terminate, and provide for payback of a NRSA. Closeout of an award requires a Final Invention Statement (HHS 568) and Final Progress Report. iEdison allows grantees and federal agencies to meet statutory requirements for reporting inventions and patents. The PHS 3734 serves as the official record of grantee relinquishment of a PHS award when an award is transferred from one grantee institution to another. The SBIR/STTR Life Cycle Certifications are completed by small business grantees once certain milestones are reached during the project period. Pre-award reporting requirements are simultaneously consolidated under 0925–0001.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 531,802.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Information collection forms	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
<b>Reporting</b>				
PHS 416–7 .....	12,580	1	30/60	6,290
PHS 6031–1 .....	1,778	1	20/60	593
PHS 568 .....	11,180	1	5/60	932
iEdison .....	5,697	1	15/60	1,424
PHS 2271 .....	22,035	1	15/60	5,509
PHS 2590 .....	243	1	15	3,645
RPPR .....	32,098	1	15	481,470
Biosketch .....	2,544	1	2	5,088
Data Tables .....	758	1	4	3,032
PHS Inclusion Enrollment Report .....	2,544	1	1	2,544
Trainee Diversity Report .....	480	1	15/60	120
Publication Reporting .....	32,341	3	5/60	8,085
PHS 3734 .....	479	1	30/60	240
Final Progress Report .....	11,125	1	1	11,125
SBIR/STTR Phase II Final Progress Report .....	1,330	1	1	1,330
<b>Reporting Burden Total</b> .....				<b>531,427</b>
<b>Recordkeeping</b>				
SBIR/STTR Life Cycle Certification .....	1,500	1	15/60	375
<b>Grand Total</b> .....				<b>531,802</b>

Dated: July 29, 2015.

**Lawrence A. Tabak,**

*Deputy Director, National Institutes of Health.*

[FR Doc. 2015-19253 Filed 8-4-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary and Integrative Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Complementary and Integrative Health.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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:* National Advisory Council for Complementary and Integrative Health.

*Date:* August 26, 2015.

*Open:* 1:00 p.m. to 1:15 p.m.

*Agenda:* Concept Review—Mechanistic Studies of Complementary and Integrative Mind and Body and Body Interventions Supported by NCCIH.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Closed:* 1:20 p.m. to 2:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Martin H. Goldrosen, Ph.D., Director, Division of Extramural Activities, National Center for Complementary and Integrative Health, NIH, 6707 Democracy Blvd., Ste. 401, Bethesda, MD 20892-5475, (301) 594-2014, [goldrosen@mail.nih.gov](mailto:goldrosen@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://nccih.nih.gov/about/naccih>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: July 30, 2015.

**Michelle Trout,**

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

[FR Doc. 2015-19174 Filed 8-4-15; 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 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:* National Institute on Aging Special Emphasis Panel; Albert Einstein Aging Study.

*Date:* September 17, 2015.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Carmen Moten, MPH, Ph.D., Scientific Review Officer, National

Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7703, [cmoten@mail.nih.gov](mailto:cmoten@mail.nih.gov).

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

Dated: July 31, 2015.

**David Clary,**

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

[FR Doc. 2015-19192 Filed 8-4-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30 Day Comment Request; PHS Applications and Pre-Award Reporting Requirements (OD/OPERA)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act (PRA) of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 16, 2015, Volume 80, No. 50, pages 13567-13568 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be sent via email to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: Desk Officer for NIH.

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie,