As described in this document, the application holders agreed to voluntarily remove their respective 32 mg, single IV dose ondansetron products from the market, and requested that FDA withdraw approval of their respective applications (listed in the preceding table) under § 314.150(d) (21 CFR 314.150(d)). On December 4, 2012, FDA issued an updated Drug Safety Communication alerting health care professionals that these products would be removed from the market because of their potential for serious cardiac risks.

Baxter's Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, was approved in NDA 021915 on December 27, 2006. In a letter dated November 27, 2012, Baxter requested withdrawal of NDA 021915 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a). In a letter dated September 5, 2012, Baxter notified FDA that the product was being discontinued. In a contemporaneous notice, FDA is announcing its determination that the product was withdrawn from sale for reasons of safety or effectiveness and that FDA will not accept or approve ANDAs that refer to this drug product.

Hospira's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 077348 on February 1, 2007. In a letter dated January 31, 2013, Hospira requested withdrawal of ANDA 077348 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Teva's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 077480 on November 22, 2006. In a letter dated November 20, 2012, Teva requested withdrawal of ANDA 077480 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Bedford's ondansetron HCl Injection 32 mg/50 mL, single IV dose was approved in ANDA 078291 on April 13, 2009. In a letter dated April 4, 2014, Bedford requested withdrawal of ANDA 078291, under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Claris's ondansetron HCl Injection 32 mg/50 mL, single IV dose, was approved in ANDA 078308 on March 17, 2008. In a letter dated November 16, 2012, through its U.S. agent, CUSTOpharm, Inc., Claris requested withdrawal of ANDA 078308 under 21 CFR 314.150(d), and waived its opportunity for a hearing provided under § 314.150(a).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and 21 CFR 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of the applications listed in the table of this document, and all amendments and supplements thereto, is withdrawn (see **DATES**). Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)). The Agency will remove these products from the list of drug products with effective approvals published in FDA's ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' generally referred to as the ''Orange Book.''

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14144 Filed 6–9–15; 8:45 am]

BILLING CODE 4164–01–P

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 Conflict: Dry Eye and Lacrimal Gland.

Date: June 15, 2015.

Time: 4:00 p.m. to 6:00 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: Alessandra C Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm 5205 MSC7846, Bethesda, MD 20892, (301) 435–1021, *rovescaa@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.

(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: June 5, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–14185 Filed 6–9–15; 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 (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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Infectious, Reproductive, Asthma, and Pulmonary Conditions.

Date: July 2, 2015.

Time: 12 p.m. to 3 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: Ellen K. Schwartz, Ed.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3144, MSC 7770, Bethesda, MD 20892, 301–828–6146, *schwarel@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering Sciences Member Conflict.

Date: July 7–9, 2015.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Radiation Therapy and Biology SBIR/STTR.

Date: July 8–9, 2015.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov*.

(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: June 5, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–14186 Filed 6–9–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval. This summary describes the existing information collection at ClinicalTrials.gov, for which an extension is requested; it does not include any changes to the information collection that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 (79 FR 225, Nov. 21, 2014).

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: David Sharlip, Office of Administrative and Management Analysis Services, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 402–9680, or Email your request, including your address to: *sharlipd@mail.nih.gov* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM), 0925–0586, Expiration *Date:* 08/31/2015, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (*e.g.,* observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered and submit results information voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events.

This extension request does not include any changes to the information submission requirements for ClinicalTrials.gov that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 and for which the public comment period closed on March 23, 2015 (79 FR 225, Nov. 21, 2014). The NIH is continuing to review submitted public comments as it prepares the final rule. The NIH will make any corresponding changes to the ClinicalTrials.gov information collection via separate procedure.

OMB approval is requested for 3 years. The total estimated annualized cost to respondents is $49,399,851. The total estimated annualized burden hours are 682,535.

ESTIMATED ANNUALIZED BURDEN HOURS

Submission type	Number of respondents	Number of response per respondent	Average time per response	Annual hour burden
PRS Account	5,700	1	15/60	1,425
Initial Registration	*23,000*	*1*	*7*	*161,000*
Updates	*23,000*	*8*	*2*	*368,000*
Initial Results	*3,700*	*1*	*25*	*92,500*
Updates	*3,700*	*2*	*8*	*59,200*