

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 In a contemporaneous notice, FDA is announcing its determination that the product was withdrawn from sale for reasons of safety or effectiveness and that FDA will not accept or approve ANDAs that refer to this drug product.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.*

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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 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](mailto: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.*

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## 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.

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*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](mailto: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).