

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity or type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Focus Group Subjects	20	0.33	7	1.5	10
Total	49,310	8,038

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

* Includes a total of 8 experimental or observational studies over a 3-year period for each of the 4,000 panel members who are active at the time of each study. The first study (Study 1) is included in this clearance request; the remaining studies will be funded under separate task orders but are included in this table to present an overall estimate of the burden for each participating panel member.

** Assumes 1,400 additional panel members will be recruited annually (2,800 total) as part of the panel replenishment effort.

The collection burden was estimated using data from timed-readings of each instrument, including the mail and field screeners, enrollment survey, baseline survey, panel maintenance questionnaires, and Study 1 questionnaire.

References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. Baker, R., Blumberg, S., Brick, M., Couper, M., Courtright, M., Dennis, J. M., Dillman, D., Frankel, M., Garland, P., Groves, R., Kennedy, C., Krosnick, J. and Lavrakas, P., 2010, American Association for Public Opinion Research Report on Online Panels. *Public Opinion Quarterly*, 74 (4), pp. 711–781.
2. Coen, T., Lorch, J. and Piekarski, L., 2005, The Effects of Survey Frequency on Panelists' Responses, *Worldwide Panel Research: Developments and Progress*, Amsterdam, European Society for Opinion and Marketing Research.
3. Nancarrow, C. and Catwright, T., 2007, Online Access Panels and Tracking Research, *The Conditioning Issue, International Journal of Market Research*, 49(5), pp. 435–447.
4. Kruse, Y., Callegaro, M., Dennis, J. M., DiSogra, C., Subias, S., Lawrence, M.,

and Tompson, T., 2009, Panel Conditioning and Attrition in the AP-Yahoo! News Election Panel Study, Paper presented at the American Association for Public Opinion Research 64th Annual Conference.

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14125 Filed 6–9–15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-1702]

Baxter Healthcare Corporation et al.; Withdrawal of Approval of One New Drug Application and Four Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of one new drug application (NDA) for Ondansetron (ondansetron hydrochloride (HCl)) Injection, USP in PL 2408 Plastic Container, 32 milligrams (mg) in 50 milliliters (mL), single intravenous (IV) dose, and four abbreviated new drug applications (ANDAs) for ondansetron HCl and

Dextrose in 32 mg single IV doses. The holders of these applications have voluntarily requested that FDA withdraw approval of their applications and have waived their opportunity for a hearing.

DATES: Effective June 10, 2015.

FOR FURTHER INFORMATION CONTACT:

Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993-0002, 301-796-3381.

SUPPLEMENTARY INFORMATION: On June 29, 2012, FDA issued a Drug Safety Communication to notify health care professionals that the 32 mg, single IV dose of ondansetron HCl, indicated for prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in adult patients, should be avoided due to the risk of a specific type of irregular heart rhythm called QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm. Subsequently, FDA contacted the holders of the following applications and informed them that the Agency believes that in light of the safety concern associated with ondansetron HCl in the 32 mg, single IV dose, the following drug products should be removed from the market:

Application number	Drug	Applicant
NDA 021915	Ondansetron Hydrochloride Injection, USP premix in Intravia Plastic Container.	Baxter Healthcare Corporation (Baxter), 32650 N. Wilson Rd., Round Lake, IL 60073.
ANDA 077348	Ondansetron Hydrochloride and Dextrose in Plastic Container.	Hospira, Inc. (Hospira), 275 North Field Dr., Department 389, Bldg. H2-2, Lake Forest, IL 60045.
ANDA 077480	Ondansetron Hydrochloride and Dextrose in Plastic Container.	Teva Pharmaceuticals USA (Teva), 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.
ANDA 078291	Ondansetron Hydrochloride and Dextrose in Plastic Container.	Bedford Labs (Bedford), 300 Northfield Rd., Bedford, OH 44146.
ANDA 078308	Ondansetron Hydrochloride and Dextrose in Plastic Container.	Claris Lifesciences Ltd. (Claris), 2325 Camino Vida Roble, Suite A, Carlsbad, CA 92011.

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]

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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.

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).