DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Electronic Submission of Allegations of Regulatory Misconduct Associated With Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On May 27, 2014, the Agency submitted a proposed collection of information entitled ''Electronic Submission of Allegations of Regulatory Misconduct Associated with Medical Devices'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0769. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21769 Filed 9–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1422]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On June 30, 2014, the Agency submitted a proposed collection of information entitled ''Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0772. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21728 Filed 9–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0199]

MK Laboratories, Inc., et al.; Withdrawal of Approval of 3 Abbreviated New Drug Applications for Propoxyphene Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three abbreviated new drug applications (ANDAs) for products containing propoxyphene. The basis for the withdrawals is that the products are no longer shown to be safe because propoxyphene puts patients at risk of potentially serious and even fatal heart rhythm abnormalities. The holders of these ANDAs have waived their opportunity for a hearing.

DATES: Effective September 12, 2014.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6254, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: On November 18, 2010, after receiving clinical data and other information showing that propoxyphene puts patients at risk of potentially serious and even fatal heart rhythm abnormalities, FDA asked manufacturers of then marketed branded and generic propoxyphene drug products to voluntarily withdraw the products from the U.S. market. In a notice published in the **Federal Register** of March 10, 2014 (79 FR 13308), FDA withdrew approval of 8 new drug applications (NDAs) and 46 ANDAs for propoxyphene drug products from multiple sources whose application holders agreed in writing to waive their opportunity for a hearing and permit FDA to withdraw approval of the applications. In a separate notice published in the **Federal Register** of March 10, 2014 (79 FR 13310), FDA's Center for Drug Evaluation and Research (CDER) notified the holders of 3 other approved ANDAs for propoxyphene drug products of their opportunity to request a hearing on CDER's proposal to issue an order, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)), withdrawing approval of 3 ANDAs for propoxyphene drug products. The following products, all of which FDA

believes were discontinued prior to November 2010, were listed in the notice.

TABLE 1—PROPOXYPHENE DRUG PRODUCT APPLICATIONS FOR WHICH FDA PROPOSED TO WITHDRAW APPROVAL

Application No.	Drug	Applicant or holder
ANDA 083544	Kesso-Gesic (propoxyphene hydrochloride (HCl)) Capsules, 65 milligrams (mg).	MK Laboratories Inc., 424 Grasmere Ave., Fairfield, CT 06430.
ANDA 084551	Propoxyphene HCl Capsules, 65 mg	Whiteworth Towne Paulsen Inc.
ANDA 084553	Compound 65 (aspirin, caffeine, and propoxyphene HCl) Capsules, 389 mg/32.4 mg/65 mg.	Alra Labs, 3850 Clearview Ct., Gurnee, IL 60031.

In its March 10, 2014, notice of opportunity for a hearing, CDER provided these ANDA holders an opportunity to request a hearing to show why approval of the ANDAs should not be withdrawn. No timely request for a hearing on this matter was received following publication of the notice in the **Federal Register**.

Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs, approval of the applications listed in table 1 and all amendments and supplements thereto is withdrawn (see **DATES**). Introduction or delivery for introduction of these products into 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. 331(d))).

Dated: September 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21729 Filed 9–11–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. This meeting was announced in the **Federal Register** of April 25, 2014 (79 FR 22995). The amendment is being made to reflect a change in the *Agenda* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 25, 2014, FDA announced that a meeting of the Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee would be held on October 16, 2014. On page 22996, in the first column, the *Agenda* portion of the document is changed to read as follows:

Agenda: The committees will discuss safety data from observational studies and a meta-analysis of randomized controlled clinical trials that have been conducted since the original signal of serious neuropsychiatric adverse events with CHANTIX (varenicline tartrate tablets, NDA 21928, Pfizer, Inc.) emerged. The committees will also discuss whether any action needs to be taken with regard to how this risk is described in product labeling.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: September 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21780 Filed 9–11–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Food and Drug Administration (FDA) and the National Cancer Institute (NCI) Health Communication Survey (FDA–NCI)

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 May 8, 2014, Vol. 79, No. 89, page 26439 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 National Cancer Institute (NCI), National Institutes of Health, 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: NIH Desk Officer.

DATES: *Comment 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 obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Bradford W. Hesse, Ph.D., Health Communication and Informatics Research Branch, 9609 Medical Center