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