DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1663]

Determination That Ondansetron (Ondansetron Hydrochloride) Injection, USP in PL 2408 Plastic Container, 32 Milligrams in 50 Milliliters, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Ondansetron (ondansetron hydrochloride (HCl)) Injection, USP in PL 2408 Plastic Container, 32 milligrams (mg) in 50 milliliters (mL), single intravenous (IV) dose, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose.

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: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show among other things that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, is the subject of NDA 021915, held by Baxter Healthcare Corporation (Baxter), and initially approved on December 27, 2006. The product is indicated for prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy in adult patients. It was approved under the pathway described by section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(2)). Baxter's application relied in part on FDA's finding of safety and effectiveness for ZOFRAN, NDA 020007, held by GlaxoSmithKline (GSK).

In September 2011, FDA issued a Drug Safety Communication noting concerns that the 32 mg single IV dose of ZOFRAN, NDA 020007, and generic versions of that product could increase the risk of abnormal changes in the electrical activity of the heart, which could result in a potentially fatal abnormal heart rhythm. Specifically, the Agency noted that the 32 mg single IV dose of ondansetron could cause QT prolongation, which can lead to a serious and sometimes fatal heart rhythm called Torsades de Pointes. At FDA's request, GSK conducted a study to assess that risk. That study identified a significant QT prolongation effect in connection with the 32 mg single IV dose of Ondansetron. Based on this data, FDA approved GSK's supplemental application to remove the 32 mg single IV dose information from the labeling for ZOFRAN and has worked with manufacturers of all 32 mg, single IV dose ondansetron products to have them removed from the market.

In a letter dated September 5, 2012, Baxter notified FDA that Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, was being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated November 27, 2012, Baxter requested withdrawal of NDA 021915 for Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose. In a contemporaneous notice, FDA is announcing that it is withdrawing approval of NDA 021915.

We have carefully reviewed our files for records concerning the withdrawal of Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, from sale. We have also evaluated relevant literature and data. FDA has determined under §§ 314.161 and 314.162(a)(2), that Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, was withdrawn from sale for reasons of safety.

Accordingly, the Agency will remove Ondansetron (ondansetron HCl) Injection, USP in PL 2408 Plastic Container, 32 mg/50 mL, single IV dose, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14145 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–2014–N–0554]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements'' 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 April 23, 2015, the Agency submitted a proposed collection of information entitled, ''Comparative Price Information in Direct-to-Consumer and Professional Prescription Drug Advertisements'' 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 0910–0791. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14122 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–0684]

Identification of Alternative In Vitro Bioequivalence Pathways Which Can Reliably Ensure In Vivo Bioequivalence of Product Performance and Quality of Non-Systemically Absorbed Drug Products for Animals; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period related to the use of in vitro methods as a mechanism for assessing the in vivo product bioequivalence (BE) of nonsystemically absorbed drug products intended for use in veterinary species, published in the **Federal Register** of March 18, 2015 (80 FR 14146). FDA is reopening the comment period to update comments and to receive any new information.

DATES: Submit either electronic or written comments by August 10, 2015.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Harshman, Center for Veterinary Medicine, Food and Drug Administration, HFV–170, MPN2, 7500 Standish Pl., Rockville, MD 20855, 240–402–0845.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 18, 2015 (80 FR 14146), FDA announced a public meeting to discuss the use of in vitro methods as a mechanism for assessing the in vivo product bioequivalence (BE) of nonsystemically absorbed drug products intended for use in veterinary species. In the same notice, FDA said that it is seeking additional public comment to the docket. Interested persons were originally given until May 18, 2015, to comment on this issue.

II. Request for Comments

Following publication of the March 18, 2015, notification of public meeting and request for comments, FDA received a request to allow interested persons additional time to comment. The requester asserted that the time period of 60 days was insufficient to respond fully to FDA's specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

III. How To Submit Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: June 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14101 Filed 6–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1533]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment of a Tobacco User Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 10, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Establishment of a Tobacco User Panel''. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Establishment of a Tobacco User Panel—(OMB Control Number 0910–NEW)

The Food and Drug Administration's Center for Tobacco Products (CTP) proposes to establish a high quality, probability-based, primarily Web-based, panel of 4,000 tobacco users. The panel will include individuals who can participate in up to 8 studies over a 3-year period to assess consumers' responses to tobacco marketing, warning statements, product labels, and other communications about tobacco products. CTP proposed the establishment of the panel of consumers