



ANDA 090713

**ANDA APPROVAL**

Teva Pharmaceuticals USA  
425 Privet Road  
Horsham, PA 19044  
Attention: Cory Wohlbach  
Director, Regulatory Affairs

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on August 20, 2008, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials.

Reference is also made to the tentative approval letter issued by this office on April 5, 2012, the complete response letter issued by this office on May 1, 2014, and to your amendments dated July 31, September 22 and October 9, 2014; April 13 and April 28, 2015.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. **Accordingly the ANDA is approved**, effective on the date of this letter. The Division of Bioequivalence has determined your Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Aloxi Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials, of Helsinn Healthcare SA (Helsinn).

The reference listed drug (RLD) upon which you have based your ANDA, Helsinn's Aloxi (palonosetron hydrochloride) Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
7,947,724 (the '724 patent)	July 30, 2024*
7,947,725 (the '725 patent)	July 30, 2024*
7,960,424 (the '424 patent)	July 30, 2024*
8,518,981 (the '981 patent)	July 30, 2024*
8,598,218 (the '218 patent)	July 30, 2024*
8,598,219 (the '219 patent)	July 30, 2024*
8,729,094 (the '094 patent)	July 30, 2024* (0.25 mg/5 mL only)
9,066,980 (the '980 patent)	January 30, 2024 (0.25 mg/5 mL only)

9,125,905 (the '905 patent)

January 30, 2024

\*with pediatric exclusivity added

With respect to the '724, '725, '424 '981, '218, '219, '094, 980 and '905 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials under this ANDA. You have notified the agency that Teva complied with the requirements of section 505(j)(2)(B) of the FD&C Act. The agency notes that these patents were submitted to the agency after submission of your ANDA and therefore litigation, if any, with respect to these patents creates no statutory stay of approval.

With respect to 180-day generic drug exclusivity, we note that Teva was one of the first ANDA applicants with a substantially complete ANDA for Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL and 0.075 mg (base)/1.5 mL single-use vials, to submit a paragraph IV certification. Therefore, with this approval, Teva may be eligible for 180 days of shared generic drug exclusivity for Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL single-use vials, and is eligible for 180 days of shared generic drug exclusivity for Palonosetron Hydrochloride Injection, 0.075 mg (base)/1.5 mL single-use vials. The agency notes that Teva failed to obtain tentative approval of the 0.25 mg (base)/5 mL strength single-use vials, within the relevant time period after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the FD&C Act (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Teva's eligibility for 180-day exclusivity for the 0.25 mg (base)/5 mL strength.

At least one first applicant remains eligible for 180 days of generic drug exclusivity for Palonosetron Hydrochloride Injection, 0.25 mg (base)/5 mL single-use vials. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the date of the commercial marketing by any first applicant, as identified in section 505(j)(5)(B)(iv) of the FD&C Act. Please submit correspondence to this ANDA informing the agency of the date you begin commercial marketing.

Under section 506A of the FD&C Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory

requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion  
5901-B Ammendale Road  
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

**Carol A. Holquist -S**

Digitally signed by Carol A. Holquist -S  
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,  
0.9.2342.19200300.100.1.1=1300052464, cn=Carol A. Holquist -S  
Date: 2015.10.13 15:54:36 -04'00'

Carol A. Holquist, RPh  
Acting Deputy Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research