ANDA 091483

OFFICE OF GENERIC DRUGS

Office of Generic Drugs (HFD–600)
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North VII
7620 Standish Place
Rockville,MD 20855
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Amneal Pharmaceuticals TEL: (908) 231-1072

ATTN: ~~Chintu Patel~~ ELUCH PATEL FAX: ~~(908) 231-1085~~ ~~908-231-1044~~

FROM: Frank J. Nice FDA CONTACT PHONE: (240) 276-8555

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated , submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ondansetron Oral Solution, USP 4 mg/5 mL.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091483

Amneal Pharmaceuticals
Attention: Shreena Patel
Project Manager, Regulatory Affairs
85 Adams Avenue
Hauppauge, NY 11788

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 28, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ondansetron Oral Solution USP, 4 mg/5 mL.

Reference is also made to your amendments dated February 17, July 29, November 9, and December 14, 2010.

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 Ondansetron Oral Solution USP, 4 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zofran Oral Solution, 4 mg/5 mL, of GlaxoSmithKline (GSK).

The RLD upon which you have based your ANDA, GSK's Zofran Oral Solution, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,854,270 (the '270 patent) is scheduled to expire on May 20, 2016 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '270 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ondansetron Oral Solution USP, 4 mg/5 mL, under this ANDA. You have notified the agency that

Amneal Pharmaceuticals (Amneal) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Amneal within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

Under section 506A of the 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 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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

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/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

(See appended electronic signature page)

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST
01/31/2011
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.