DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090216

Wockhardt USA LLC
U.S. Agent for : Wockhardt Limited
Attention: Leanne Usa
20 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

RECEIVED BY
MAY 24 2010
Regulatory Affairs

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 11, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Valacyclovir Hydrochloride Tablets, 500 mg (base) and 1 g (base).

Reference is also made to your amendments dated January 21, and June 11, 2008; January 7, June 12, and July 9, 2009; March 29, April 27, April 28, and May 20, 2010. Reference is also made to your communications dated June 11, 2008 and May 18, 2010, pertaining to the patent and exclusivity issues associated with this ANDA.

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 Valacyclovir Hydrochloride Tablets, 500 mg (base) and 1 g (base) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Valtrex Caplets 500 mg (base) and 1 g (base), respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Valtrex Caplets, 500 mg (base) and 1 g (base) of GlaxoSmithKline (GSK), is subject to periods of patent protection with pediatric exclusivity included. As noted in the

agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,879,706 (the `706 patent) and 6,107,302 (the `302 patent) are scheduled to expire on July 19, 2016.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Valacyclovir Hydrochloride Tablets, 500 mg (base) and 1 g (base), under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Wockhardt Limited (Wockhardt) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against Wockhardt prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Wockhardt complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Wockhardt within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii). Furthermore, we note that the 180-day period of generic drug exclusivity awarded by the agency to Ranbaxy Laboratories Ltd. under section 505(j)(5)(B)(iv) of the Act for this drug product has expired.

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.

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

Postmarketing reporting requirements for this ANDA application 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.

Within 14 days of the date of this letter, submit updated 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. For administrative purposes, please designate this submission as ***"LABELING/SPL FINAL for Approved ANDA 090216".***

Sincerely yours,

(See appended electronic signature page)

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90216	ORIG-1	WOCKHARDT LTD	VALACYCLOVIR HYDROCHLORIDE

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
05/24/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.