DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 090786

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on August 5, 2008, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/ 50 mg/200 mg.

Reference is also made to your amendments dated December 4, 2008; October 7, 2009; December 30, 2010; March 11, June 10, June 28, October 12, October 17, and December 24, 2011; February 3, March 7, and November 15, 2012.

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 Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Stalevo-50 Tablets (12.5 mg/50 mg/200 mg) of Orion Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Stalevo-50 Tablets, of Orion Corporation (Orion), is subject to periods of patent protection. The following patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,446,194 (the '194 patent)	October 19, 2013
6,500,867 (the '867 patent)	June 29, 2020
6,797,732 (the '732 patent)	June 29, 2020

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, under this ANDA. You have notified the agency that Wockhardt Limited (Wockhardt) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Wockhardt for infringement of the '194 and '867 patents within the statutory 45-day period in the United States District Court for the District of Delaware [Orion Corporation v. Wockhardt USA, Inc. a/k/a Wockhardt USA, LLC and Wockhardt Limited, Civil Action No. 08-917-GMS-LPS]. You have also notified the agency that this litigation has been dismissed.

With respect to 180-day generic drug exclusivity, we note that Wockhardt was the first ANDA applicant for Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Wockhardt may be eligible for 180 days of generic drug exclusivity for Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). (b) (4) The agency is not, however, making a formal determination at this time of Wockhardt's eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Wockhardt begins commercial marketing of each of Carbidopa, Levodopa and Entacapone Tablets, 12.5 mg/50 mg/200 mg, or (b) at any time prior to the expiration of the '867 and '732 patents if Wockhardt has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Your ANDA is now subject to facility fees. You must pay fees in accordance with the Generic Drug User Fee Amendments of 2012 (Public Law 112-144, Title III). You will not be penalized for nonpayment of the facility fee until the fee payment is overdue. The fee must be paid by the date listed in the Federal Register (FR) notice announcing the facility fee amount. If the facility fee is not paid by the due date, statutory penalties take effect. At that time, FDA will deem misbranded this ANDA product and all products from facilities that have not paid the appropriate fee. In addition, the facilities will be placed on a publicly available arrears list, until the fee is paid or the facilities are removed from the ANDA.

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
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.

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,

{See appended electronic signature page}

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
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

11/20/2012

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.