DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090145

Novel Laboratories, Inc.
Attention: Anu Radha Subramanian, Esq.
Head of Regulatory Affairs
400 Campus Drive
Somerset, NJ 08873

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 26, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid for Oral Solution.

Reference is also made to the tentative approval letter issued by this office on May 25, 2010, and to your amendments dated September 14, 2010; and November 15, and November 29, 2011.

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 Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid for Oral Solution to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), MoviPrep for Oral Solution of Salix Pharmaceuticals, Inc. (Salix).

The RLD upon which you have based your ANDA, Salix's MoviPrep for Oral Solution, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 7,169,381 (the '381 patent) and 7,658,914 (the '914 patent) are both scheduled to expire on September 1, 2024.

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid for Oral Solution, under this ANDA. Of the patents listed above, only the '381 patent was listed in the Orange Book when your ANDA was received; your paragraph IV certification to the '914 patent was submitted in an amendment to your ANDA. You have notified the agency that Novel Laboratories, Inc. (Novel) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Novel for infringement of the '381 patent within the statutory 45-day period in the United States District Court for the District of New Jersey [Salix Pharmaceuticals, Inc. v. Novel Laboratories, Inc., Civil Action No. 08-CV-2311-FLW-TJB]. The 30-month stay of approval associated with this litigation has expired.

With respect to 180-day generic drug exclusivity, we note that Novel was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '381 patent. Therefore, with this approval, Novel is eligible for 180 days of generic drug exclusivity for Polyethylene Glycol 3350, Sodium Sulfate, Sodium Chloride, Potassium Chloride, Sodium Ascorbate, and Ascorbic Acid for Oral Solution. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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 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/UCM072392.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
01/25/2012
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.