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APPLICATION NUMBER:

ANDA 091559

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091559

Suven Life Sciences USA, LLC
U.S. Agent for: Suven Life Sciences Limited
Attention: Pardhasaradhi Uppalapati
1100 Cornwall Road
Monmouth Junction, NJ 08852

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 18, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Malathion Lotion USP, 0.5%.

Reference is also made to your amendments dated February 2, and April 16, 2010; August 31, 2011; and January 30, and April 3, 2012. We also acknowledge receipt of your correspondences dated September 5, 2009; March 16, March 30, June 24, and September 28, 2011; and January 18, 2012, addressing patent 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 Malathion Lotion USP, 0.5%, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Ovide Lotion, 0.5% of Taro Pharmaceuticals North America, Inc. (Taro).

The RLD upon which you have based your ANDA, Taro's Ovide Lotion, 0.5%, 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. 7,560,445 (the '445 patent) and 7,977,324 (the '324 patent) are scheduled to expire on February 1, 2027, and August 14, 2026, respectively.

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 Malathion Lotion USP, 0.5%, under this ANDA. You have notified the agency that Suven Life Sciences Limited (Suven) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '445 and '324 patents was brought against Suven in the United States District Court for the District of New Jersey [Taro Pharmaceuticals North America, Inc. v. Suven Life Sciences Limited, Civil Action No. 3:11-cv-02452-JAP]. Although this litigation remains ongoing, the '445 and '324 patents were listed after submission of your ANDA. For this reason, there is no statutory basis for litigation with respect to the '445 and '324 patents to be a bar to immediate approval of your ANDA. See section 505(j)(5)(B)(iii) of the Act.

Suven was the first applicant to submit a substantially complete ANDA with paragraph IV certifications to the '445 and '324 patents. As a first applicant, therefore, Suven may be eligible for 180 days of generic drug exclusivity for Malathion Lotion USP, 0.5%. 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. The agency notes that Suven failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Suven's eligibility for 180-day generic drug exclusivity. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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}

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

05/23/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.