DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 11-366/S-028

SUPPLEMENT APPROVAL

Taro Pharmaceutical Industries, Ltd
c/o Taro Pharmaceuticals USA, Inc.
Attention: Kavita Srivastava
Executive Director, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Ms. Srivastava:

Please refer to your Supplemental New Drug Application (sNDA) dated August 18, 2009, received August 20, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Daranide (dichlorphenamide tablets) 50 mg.

We acknowledge receipt of your amendments dated September 15, 2011, and February 27, 2012.

The September 15, 2011, submission constituted a complete response to our September 30, 2010, action letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change to the drug product manufacturing site (b) (4) to Taro Pharmaceutials, Inc. in Haifa, Israel. In addition, this submission includes a revision of the package insert to the Physician's Labeling Rule (PLR) format.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the enclosed immediate container label as soon as it is available, but no more than 30 days after it is printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Product Correspondence – Final Printed Carton and Container Labels for approved NDA 11-366/S-028." Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions regarding this supplemental application, please contact Ms. Leanna M. Kelly, Consumer Safety Officer, at (301) 796-0471. For all other inquiries regarding this NDA, call Ms. Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES: Content of Labeling and Container Labeling

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

/s/

WILEY A CHAMBERS
03/16/2012