



NDA 22067/S-007

SUPPLEMENT APPROVAL

Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive
Hawthorne, NY 10532

Attention: Kavita Srivastava
Executive Director, Regulatory Affairs

Dear Ms. Srivastava:

Please refer to your Supplemental New Drug Application (sNDA) dated, December 13, 2010, received December 14, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Flo-Pred™ (prednisolone acetate) Oral Suspension 15 mg/5 ml.

We acknowledge receipt of your amendments dated, April 11 and June 13, 2011.

This “Changes Being Effected” supplemental new drug application provides for the following labeling changes:

1. Inclusion of patient instructions for use with the oral syringe that is consistent with the instructions geared towards health professionals and suitable for consumers.
2. Relocation the instruction for using the oral syringe for healthcare professionals from the How Supplied section of the package insert to the Dosage and Administration and Patient Counseling Information sections of the package insert.
3. Revision of the How Supplied section to state, “Flo-Pred is supplied with an oral syringe”.

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, text for the

instructions for use), 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).

REPORTING REQUIREMENTS

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, call Carol F. Hill, Senior Regulatory Health Project Manager, at (301) 796-1226.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary, Allergy, and Rheumatology
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling
Package Insert and Instructions for Use.

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

/s/

CAROL F HILL
06/14/2011

BADRUL A CHOWDHURY
06/14/2011