CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-067

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-067

Taro Pharmaceuticals, USA, Inc.
3 Skyline Drive
Hawthorne, NY 10532

Attention: Srinivas Rao, Pharm.D.
Director, Regulatory Affairs

Dear Dr. Rao:

Please refer to your new drug application (NDA) dated August 11, 2006, received August 14, 2006, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Flo-Pred (prednisolone acetate oral suspension) 5 mg/5 mL and 15 mg/5 mL.

We acknowledge receipt of your submissions dated October 2 and November 22, 2006, and March 12, May 23 and 30, June 26, July 11, and September 10, 2007.

We have completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit revised draft labeling identical to the enclosed labeling and revise your carton and container labels as indicated below:

1. The proposed tradename Flo-Pred [redacted] b(4)

2. The two dosing spoons should be attached to minimize loss of a spoon and the colors should be accurately reflected on the labels.

3. Revise the Attention statement on all the panels to read "The product is packaged with one purple (2.5 mL) and one blue (5 mL) spoons for accurate dosing. Use the appropriate spoon(s) based on your prescription. Can also be used with an [redacted] syringe."

If additional information relating to the safety or effectiveness of this/these drug(s) becomes available, revision of the labeling may be required.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, call Parinda Jani, Chief of Project Management Staff, at (301) 796-1232.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, M.D.
Deputy Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

16 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Approvable Letter- 1

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/s/

Rigoberto Roca
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