DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021143/S-012

SUPPLEMENT APPROVAL

Taro Pharmaceuticals USA, Inc.
Attention: Kavita Srivastava
Executive Director, Regulatory Affairs
3 Skyline Drive
Hawthorne, NY 10532

Dear Dr. Srivastava:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 25, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trivagizole 3™ Vaginal Cream (clotrimazole vaginal cream USP) 2%.

This "Prior Approval" supplemental new drug application proposes adding an indication for external use, as well as revised directions for use regarding external and internal use. The changes were initially submitted in the June 9, 2014 annual report; however, the types of changes submitted are not allowable as annual reportable changes.

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

We remind you to contact FDA to discuss the appropriate regulatory pathway to modify the tamper-evident feature for this drug product.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the following submitted labeling and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- 21 g immediate container (tube) submitted on February 25, 2016
- 21 g tube Consumer Education Leaflet (Educational brochure) , and the 21 g outer container (carton)submitted on May 24, 2016

The final printed labeling should be submitted 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 "**Final Printed Labeling for approved NDA 021143/S-012**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Carton 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/

KAREN M MAHONEY
08/25/2016