21143

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-143

Trade Name: Trivagizole 3 Vaginal Cream 2%

Generic Name: clotrimazole vaginal cream 2%

Sponsor: Taro Pharmaceuticals, USA, Inc.

Approval Date: April 12, 2000

Indications: Treatment of vaginal yeast infections.

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI				
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)				
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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-143

APR 12 2000

Taro Pharmaceuticals U.S.A., Inc.
Attention: Lorraine W. Sachs, RAC
Associate Director, Regulatory Affairs
5 Skyline Drive
Hawthorne, NY 10532

Dear Ms. Sachs:

Please refer to your new drug application (NDA) dated June 16, 1999, received June 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trivagizole 3™ Vaginal Cream (clotrimazole vaginal cream), 2%.

We acknowledge receipt of your submissions dated:

July 16, 1999	January 5, 2000	March 20, 2000 (2)
August 12, 1999	January 19, 2000	March 22, 2000
August 25, 1999	February 3, 2000 (2)	March 31, 2000
November 17, 1999	March 8, 2000	April 3, 2000
December 20, 1999	March 17, 2000	

This new drug application provides for the use of Trivagizole 3™ Vaginal Cream (clotrimazole vaginal cream), 2% as an over-the-counter regimen for the treatment of vaginal yeast infections.

We have completed the review of this application, as amended, and we have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (package insert, immediate container, and carton labels submitted March 22, 2000), and must be formatted consistent with the requirements of 21 CFR 201.66. Marketing the product with FPL that is not identical to the approved labeling text and "Drug Facts" format may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as they are available, in no case more than 30 days after they are printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-143." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit two copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Over-the-Counter Drug Products (DOTCDP) and one copy to the Division of Special Pathogen and Immunologic Drug Products (DSPIDP). For administrative purposes, this submission should be sent to the NDA and should be identified as new correspondence to approved NDA 21-143.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). The submitted over-the-counter product labeling provides directions for use by children 12 years and over. We are waiving the pediatric study requirement for children under 12 years old on the basis that vaginal yeast infection in the pre-pubertal child does not lend itself to self-diagnosis and over-the-counter treatment.

Please submit two market packages of the drug product, when they are available, to each of the two Divisions (DOTCDP and DSPIDP).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products (DOTCDP). If you have any questions, please contact Daniel Keravich, M.S., M.B.A., Regulatory Project Manager, at (301) 827-2248.

Sincerely yours,

/S/

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

/S/

Charles Ganley, M.D.
Director
Division of Over-the-Counter
Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research