ANDA 75-915 November 21, 2001

L. Perrigo Company
Attention: Brian R. Schuster
515 Eastern Ave.
Allegan, MI 49010

Dear Sir:

This is in reference to your abbreviated new drug application dated June 26, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Tioconazole Vaginal Ointment, 6.5% (OTC).

Reference is also made to your amendments dated October 12, 2000; February 1, March 5, May 15, May 29, August 14, September 13, October 2, and October 11, 2001.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted over-the-counter (OTC) labeling. Accordingly the application is approved. The Division of Bioequivalence has determined your Tioconazole Vaginal Ointment, 6.5%, to be bioequivalent to the listed drug (Vagistat®-1 Vaginal Ointment, 6.5%, of Bristol Myers Squibb Co).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research