CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-676

PHARMACOLOGY REVIEW(S)

D/V

M E M O R A N D U M

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation & Research

Date: April 25, 1996

To: NDA 20-676

From: Team Leader-Pharmacology, Division of Anti-infective Drug Products, HFD-520

Subject: New Drug Application # 20-676 (Vagistat-1 Vaginal Ointment)

The above New Drug Application has been requested by the sponsor to undergo a change in marketing status from prescription to over-the-counter (OTC) for the treatment of recurrent vulvovaginal candidiasis.

A full review of the safety package for this NDA is not necessary because of the adequacy of the originally reviewed toxicology data used to support registration. Furthermore, human use of the product for many years has provided a satisfactory safety profile for the drug. Thus, its switch from Rx to OTC status should be allowed from a pharmacology/toxicology point of view.

Robert E. Osterberg, Ph.D.