

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-329

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY FOR 75-329

ANDA: 75-329

FIRM: L. Perrigo Company

DRUG: Miconazole Nitrate Combination Pack-2%, 200mg

DOSAGE: Cream and Suppository

STRENGTH: 2% Cream, 200mg Suppository

CGMP STATEMENT/EIR UPDATE STATUS: EER is satisfactory
11/16/98

BIO STUDY/BIOEQUIVALENCE STATUS: Bio is satisfactory 3/8/99

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has submitted satisfactory 3 months accelerated stability data at 40°C/75%RH and 18 months room temperature (25°-30°C) for suppositories. Also, 3 months accelerated stability data at 40°C/75%RH and six months room temperature (25-30°C) for cream were provided.

LABELING REVIEW STATUS: Labeling is satisfactory 10/6/98

STERILIZATION: N/A

BATCH SIZES: The firm has submitted the manufacturing instruction for intended production batch and a copy of the executed batch record lot #5M0520 for for suppository.
The firm has provided the manufacturing procedure for intended production batch of , and a copy of the exhibit batch lot #6x500v for for cream. The firm will be using the same drug substance manufacturer's DMF for the cream. The DMF is satisfactory and DMF for the suppositories. The DMF is satisfactory. The firm will be using the same equipment and manufacturing procedure.

COMMENTS: The Application is Approvable.

Reviewer: Nashed E. Nashed, Ph.D.

Date: 3/18/99

Supervisor: Paul Schwartz, Ph.D.

Date: 4/12/99

PS 4/3/00