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RESEARCH**

APPLICATION NUMBER:
21-308

PHARMACOLOGY REVIEW

PHARMACOLOGY/TOXICOLOGY REVIEW AND EVALUATION

NDA Number: 21-308

Date of submission: September 1, 2000

Information to sponsor: Yes () No (x)

Sponsor: Personal Products Company.
199 Grandview Road
Skillman, New Jersey 08558

Reviewer name: Owen McMaster, Ph.D.

Division name: Division of Special Pathogen and Immunologic Drug Products, HFD-590

Review completion date: June 20, 2001

Drug: MONISTAT®1Combination Pack

Generic name: miconazole nitrate

Relevant NDA: 20-968

Drug class: Antifungal

Indication: Vaginal yeast infections

Clinical formulation: MONISTAT®1Combination Pack consists of miconazole nitrate soft gel vaginal insert (packaged along with an applicator) and miconazole nitrate 2% cream.

Route of administration: The soft gel vaginal insert is to be inserted into the vagina at bedtime and the cream is to be applied to any itchy irritated skin outside the vagina.

Proposed use: To treat recurrent vaginal yeast infections.

OVERALL SUMMARY AND EVALUATION:

There was no new Pharmacology or Toxicology data submitted with this NDA. Based on the available data, this is an approvable product.

Owen G McMaster, Ph.D.

Pharmacology/Toxicology Reviewer

Concurrences:

HFD-590/BalaS

HFD-590/HastingsK

cc:

HFD-590/MO/LeissaB

HFD-590/Chem/MateckaD

HFD-590/ChemTL/SchmuffN

HFD-590/Pharm/McMasterO