CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-971

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA: 74-971

DRUG PRODUCT: Ketoconazole Tablets USP, 200 mg

FIRM: Novopharm Limited

DOSAGE FORM: Tablets **STRENGTH:** 200 mg

CGMP: Statement/EIR Update status:
An EER was found to be acceptable (OC recommendation, 8/10/98)

BIO: Bioequivalence study was acceptable (Div. of Bioequivalence, 8/6/98)

VALIDATION -(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):
The drug substance and drug product are covered by compendial monographs in the USP 23. Method verification by the New York District Lab was found to be acceptable.

STABILITY: The containers used in the stability study are identical to those in the container section.

LABELING:
Container, carton and insert labeling have been found satisfactory (Labeling tentative approval summary, 3/31/98, reviewed by L. Golson)

STERILIZATION VALIDATION (IF APPLICABLE):
Non-sterile drug product. No sterilization validation study is required.

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):
The proposed production batch size is tablets for the Ketoconazole Tablets, 200 mg.
The batch size of the executed batch (lot# 3040PD) is tablets.
The Drug Master File for the drug substance is currently adequate (reviewed by Liang-Lii Huang, Ph.D., 8/7/98).

SIZE OF STABILITY BATCHES- (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):
The executed batch is the biobatch. The size of the stability batch is the same as the executed batch.

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?:
The manufacturing process of the proposed production batch is the same as the executed batch.

CHEMIST: Liang-Lii Huang, Ph.D. **DATE:** September 2, 1998
SUPERVISOR: Paul Schwartz, Ph.D. **DATE:** September 4, 1998

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Date: September 2, 1998