

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER **75042**

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY FOR 75-042

ANDA: 75-042

FIRM: Taro Pharmaceuticals Inc.

DRUG: Hydrocortisone Valerate

DOSAGE: Cream

STRENGTH: 0.2%

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 3/9/98

BIO STUDY/ BIOEQUIVALENCE STATUS: Bioequivalency is acceptable 9/2/97

METHOD VALIDATION: The drug product is compendial - the method validation is acceptable 9/26/97.

STABILITY: The firm's accelerated stability data at 40°C/75%RH has failed for 15 g tube and showed decrease in the potency for 45 g from 99.9% at initial to 90.4% at 3 month test station and for the 60 g tube from 99.9% at initial to 90.7% at 3 month test station.
The firm has provided satisfactory 18 months room temperature at 25-30°C/50-60%RH for all packaging sizes.

THE EXPIRATION DATE IS 18 MONTHS.

LABELING REVIEW STATUS: Labeling is satisfactory 3/9/98

STERILIZATION: N/A

BATCH SIZES: The firm has provided the master formula and manufacturing procedure for the intended production batch _____ Also submitted a copy of the exhibit batch lot # S133-5592 for _____ The firm will be using the same drug substance manufacture _____ The DMF is satisfactory; and will be using same equipment and procedure.

COMMENTS: The Application is Approvable.

REVIEWER: NASHED E. NASHED, Ph.D.

8/17/98
Date: 8/3/98

Supervisor: Paul Schwartz, Ph.D. 8/3/98

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D S P 8/15/98 8/20/98