CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 75043

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY FOR 75-043

ANDA: 75-043

FIRM: Taro Pharmaceuticals Inc.

DRUG: Hydrocortisone Valerate

DOSAGE: Ointment

STRENGTH: 0.2%

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 10/2/97

BIO STUDY/ BIOEQUIVALENCE STATUS: The bioequivalency is acceptable 11/7/97

METHODS VALIDATION: The drug substance is compendial, the method validation for the drug product is acceptable 11/5/97. The new method found acceptable 7/24/98

STABILITY: The firm has provided satisfactory three months accelerated stability data at 40°C/75%RH and 24 months room temperature at 25-30°C for each container.

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

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master formula and manufacturing instruction for the intended production batch . Also submitted a copy of the exhibit lot # S139-5590 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. DATE: 8/3/98 8/17/98

SUPERVISOR: Paul Schwartz, Ph.D. P S 8/10/98 8/3/98

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