CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-315

ADMINISTRATIVE DOCUMENTS

APPROVAL PACKAGE SUMMARY

ANDA #: 74-315

FIRM: Geneva DRUG: Terazosin Hydrochloride
DOSAGE: Tablets STRENGTH:1 mg, 2 mg, 5 mg and 10 mg

cGMP STATEMENT/EIR UPDATE STATUS:
cGMP: Satisfactory (page 266)
EER: satisfactory dated 07-DEC-1998; requires update.

BIO STUDY(ies)/BIOEQUIVALENCE STATUS:
Satisfactory per Bioequivalence approval letter dated April 4, 1997.

METHODS VALIDATION(Including dosage form description):
Terazosin Hydrochloride has no USP monograph. Memo from the Denver DO DD indicates the methods are satisfactory.

STABILITY(Conditions, Containers, methods):
Bio batch*
Stability specifications:
Appearance: normal
Assay:
Dissolution: NLT in min as per Bio requirement
Related compounds:
nmt each individual known impurity
nmt total unknown impurities
Nmt total impurities
Hardness: As found
Friability: nmt

* Stability batches are the same as the test batches and containers correspond to container section.

LABELING REVIEW STATUS: Satisfactory dated April 4, 1997.

STERILIZATION VALIDATION(If Applicable): N/A

BATCH SIZES:

BIO BATCH(identity #, DS source)
Batch size blets
DS source: CU Chemie Uetikon

strength	Executed batch #
1 mg	92-037
2 mg	92-038
5 mg	6493084
10 mg	92-040

PROPOSED PRODUCTION BATCH(same manuf. process, #s, quant.)
tablets for each strength.

COMMENTS: Approvable

DSGrill
12-10-98