CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74-315

CHEMISTRY REVIEW(S)

ADDENDUM TO REVIEW #7

ANDA #: 74-315 (Terazosin Hydrochloride Tablets, 1 mg, 2 mg, 5 mg and 10 mg/ Geneva)

Geneva filed a Telephone Amendment on 12/17/98 regarding polymorphism of the drug substance used to manufacture the biobatch. The original ANDA was reviewed and approved by Dave Gill. However, since Dave is still on vacation and will not be back to the office until next week, Dr. Patel asked me to review the tel.amendment for Dave.

Review:

The firm provided the following chronology of amendments submitted for this unapproved ANDA regarding the polymorphism status of the Terazosin HCL drug substance:

1/12/93: Original ANDA filed stating that the nds used to manufacture the drug product was Terazosin HCL later identified as Terazosin HCL).

1/18/96: An amendment filed to indicate that the nds has been revised from Terazosin) to Terazosin HCL) with a specs of

2/23/96: An amendment provided executed batch record with accelerated stability comparative dissolution using Terazosin HCL Request for bio waiver was also made in this submission. (This information is in the application and is not included in the tel.amendment).

12/3/96: An amendment filed to revise the polymorphism specs to "

In the 12/3/96 amendment the firm provided an FTIR method which is used to identify polymorph peaks. The absence of a definite peak at about 939 cm^{-1} indicates that no polymorph II is detected. IR spectra of Terazosin HCL and 5% Form (lot #25379) in Terazosin HCL (lot #28648) are provided.

Note:

The firm used polymorph type Terazosin HCL substance to manufacture the biobatch. Subsequently, the Terazosin HCL , was used to prepare an exhibit batch in support of the move from) to . The required stability and batch records were

provided in support of the change. The bio waiver was granted for the change. However, the bio review listed as in error. The bio review must be revised to reflect that the form as stated in the submission.

Reviewer:	Date completed:
J.Fan	12/30/98

1. CHEMIST'S REVIEW NO. 7 2. ANDA # 74-315

3. NAME AND ADDRESS OF APPLICANT
Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan
2555 W. Midway Blvd.
P.O. Box 446
Broomfield, CO 80038-0446

4. LEGAL BASIS FOR SUBMISSION Hytrin®; Abbott
5. SUPPLEMENT(s) NA
6. PROPRIETARY NAME none
7. NONPROPRIETARY NAME **Terazosin Hydrochloride Tablets**
8. SUPPLEMENT(s) PROVIDE(s) FOR: NA
9. AMENDMENTS AND OTHER DATES:
January 12, 1993 Date of application
Amendment: October 14, 1998
10. PHARMACOLOGICAL CATEGORY 11. Rx or OTC
antihypertensive Rx
12. RELATED IND/NDA/DMF(s) see section 37.
13. DOSAGE FORM 14. POTENCY
oral tablet **1 mg, 2 mg, 5 mg and 10 mg**

18. CONCLUSIONS AND RECOMMENDATIONS: **Approval**

19. REVIEWER: Dave Gill DATE COMPLETED: October 30, 1998

cc:

Endorsements:

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Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chem Rev. # 7

10/30/98