CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-641/SE5-007

Chemistry Review(s)

TROUT

DEC 14 1999

CHEMIST'S REVIEW #1

1. ORGANIZATION	2. NDA NUMBER
HFD-570 DPDP	20-641

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

4. AF NUMBER

5. SUPPLEMENT(S)
NUMBER(S) DATES(S)
SE5-007 11/24/99

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Claritin® Syrup	loratadine

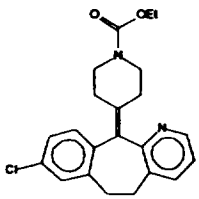
8. SUPPLEMENT PROVIDES FOR: Lowering the age of patients to include pediatric subjects of 2-5 years of age.

9. AMENDMENT(S), REPORT(S), ETC.

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED
antihistamine	RX X OTC___
13. DOSAGE FORM(S)	14. POTENCY
syrup	1 mg/mL loratadine

12. RELATED IND/NDA/DMF

15. CHEMICAL NAME AND STRUCTURE
Ethyl 4-(8-chloro-5,6-dihydro-11*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridin-11-ylidene)-1-piperidinecarboxylate



16. RECORDS AND REPORTS
CURRENT YES X NO__
REVIEWED YES__ NO X

17. COMMENTS: See attached review notes.

cc:
Orig. NDAs 20-641
HFD-570/div. File
HFD-570/CBertha/12/14/99
HFD-570/GPoochikian
HFD-570/GTrout
R/D Init. by: GP 12/14/99
F/T by: CBertha/12/14/99

18. CONCLUSIONS AND RECOMMENDATIONS: In terms of chemistry, manufacturing, and controls information, it is recommended that the supplemental application be **approved** (AP).

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		12/14/99

Redacted 1

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