

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-658/S-018

19-670/S-018

20-470/S-016

20-641/S-009

20-704/S-008

CHEMISTRY REVIEW(S)

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| CHEMIST'S REVIEW | | 1. ORGANIZATION HFD-570 DPADP | 2. NDA NUMBER 19-658 |
| 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) SE6-018(1/25/02) SE6-018[BC](3/22/02) | |
| 6. NAME OF DRUG Claritin® Tablets | 7. NONPROPRIETARY NAME loratadine | | |
| 8. SUPPLEMENT PROVIDES FOR: Supplement for Rx to OTC Switch | | | |
| 9. PHARMACOLOGICAL CATEGORY Antihistamine | 10. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/> | 11. RELATED IND/NDA/DMF NDA 20-641/SE6-009(1/25/02) NDA 20-704/SE6-008(1/25/02) | |
| 12. DOSAGE FORM(S) Tablet | 13. POTENCY 10 mg | | |
| 14. CHEMICAL NAME AND STRUCTURE See USAN Dictionary. | | 15. RECORDS AND REPORTS CURRENT YES_NO REVIEWED YES_NO | |
| 16. COMMENTS: see review notes on page 2 cc: Orig. NDA #19-658 HFD-570/Div. File HFD-570/CHKim/ HFD-570/GPoochikian HFD-570/AZeccola R/D Init. By: _____ F/T by: CHKim/ doc #: N19658.s18.doc | | | |
| 17. CONCLUSIONS AND RECOMMENDATIONS The supplement is approvable from CMC standpoint. | | | |
| 18. REVIEWER NAME Chong-Ho Kim, Ph.D. | SIGNATURE | | DATE COMPLETED 9-16-02 |

1 page(s) have been removed because it contains trade secret and/or confidential information that is not disclosable.

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/s/

Chong-Ho Kim
9/17/02 07:47:35 AM
CHEMIST

Guiragos Poochikian
9/18/02 10:04:26 AM
CHEMIST

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| CHEMIST'S REVIEW Review #1 | 1. ORGANIZATION HFD-570 DPADP | 2. NDA NUMBER 20-470 |
| 3. NAME AND ADDRESS OF APPLICANT (City and State) Schering Corporation 2000 Galloping Hill Road Kenilworth, NJ 07033 | | 4. AF NUMBER |
| 6. NAME OF DRUG CLARITIN-D 24 HOUR Extended Release Tablets | | 5. SUPPLEMENT (S) NUMBER(S) DATES(S) SE6-016 (1/25/02) SE6-016 [BC] (3/22/02) |
| 7. NONPROPRIETARY NAME loratadine 10 mg/ pseudoephedrine sulfate 240 mg | | |
| 8. SUPPLEMENT PROVIDES FOR: This supplement provides for switching the products from Rx to OTC. | | |
| 9. PHARMACOLOGICAL CATEGORY Antihistamine | 10. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/> | 11. RELATED IND/NDA/DMF NDA 19-670/SE6-018 (1/25/02) |
| 12. DOSAGE FORM(S) Tablet | 13. POTENCY loratadine 10 mg/pseudoephedrine sulfate 240 mg | |
| 14. CHEMICAL NAME AND STRUCTURE See USAN Dictionary. | | 15. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/> |
| 16. COMMENTS: see review notes on page 2 Cc: Orig. NDA #20-470 HFD-570/Div. File HFD-570/CHKim/ HFD-570/GPoochikian HFD-570/AZeccola R/D Init. By: _____ F/T by: CHKim/ Doc #: N20470SE6.016.doc | | |
| 17. CONCLUSIONS AND RECOMMENDATIONS: Chemist recommends approval of this supplement. | | |
| 18. REVIEWER NAME Chong-Ho Kim, Ph.D. | SIGNATURE | DATE COMPLETED 9-16-02 |

Claritin-D 12 Hour Extended Release Tablets (NDA 19-670/SE6-018)
Claritin-D 24 Hour Extended Release Tablets (NDA 20-470/SE6-016)

Review Notes

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/s/

Chong-Ho Kim
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CHEMIST

Guiragos Poochikian
9/18/02 10:01:14 AM
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