CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-363

Chemistry Review(s)
MEMORANDUM: DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC
HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: January 24, 2002

TO: N21-297 File
    N21-363 File

THROUGH: Guirag Poochikian, Ph.D.
          Chemistry Team Leader
          Division of Pulmonary Drug Products (HFD-570)

FROM: Craig M. Bertha, Ph.D.
      Chemistry Reviewer
      Division of Pulmonary Drug Products (HFD-570)

SUBJECT: Submissions of January 22, 2002 for both applications referenced above.

BACKGROUND:

Because of compliance problems associated with various manufacturing and testing sites for
the Clarinex Tablets (desloratadine tablets) application N21-165, the applicant withdrew the
Kenilworth, NJ site (January 10, 2001 submission) as a manufacturing site, the Singapore site
as a manufacturing site (May 22, 2001 submission), and the Union, NJ site as a
testing site (August 15, 2001 submission).

CONTENT:

The related applications N21-297 and N21-363 are for additional indications (chronic idiopathic
urticaria and allergic rhinitis, respectively). The submission of January 22, 2002 refers to the
past withdrawal of the above mentioned sites for the parent application N21-165 and states that
these site withdrawals also apply to N21-297 and N21-363. Since the action dates for these
two applications are approaching in the near future, the chemist requested through EES that
the Office of Compliance update their overall recommendation for the sites associated with
these applications on January 22, 2002. The EES lists the overall recommendation for the
N21-297 and N21-363 applications as both WITHHOLD as of July 30, 2001 and August 10,
2001, respectively, as of the date of this memorandum. The CMC team can not recommend
the approval of the applications until the OC makes a favorable recommendation.

/S/
Craig M. Bertha, Ph.D.
Chemistry Reviewer

cc:

Post memo note of 2/9/02: Once the chemist removed the
sites with compliance issues (listed in "BACKGROUND" section above)
from the EES, compliance made an overall recommendation
in N21-297 ad N21-363 of ACCEPTABLE on 1/31/02.
Orig. NDA 21-297
Orig. NDA 21-363
HFD-570/Div. Files
HFD-570/CBertha 1/24/02
HFD-570/GPoochikian
HFD-570/AZeccola
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Craig Bertha
1/24/02 12:36:29 PM
CHEMIST

Guiragos Poochikian
1/25/02 10:53:47 AM
CHEMIST
DIVISION OF PULMONARY AND ALLERGY DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

NDA #: 21-363  CHEM. REVIEW #: 1  REVIEW DATE: 5/4/01

RECOMMEND ACTION: APPROVABLE

SUBMISSION TYPE
ORIGINAL*
Amendment BC*
*Subject of this review

DOCUMENT DATE
4/10/01
4/19/01

CDER DATE
4/12/01
4/19/01

ASSIGNED DATE
4/18/01
4/19/01

NAME & ADDRESS OF APPLICANT:
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

DRUG PRODUCT NAME:
Proprietary:

Nonproprietary/USAN:
desloratadine 5 mg tablet (film coated)

Code Name/#:
SCH 34117

Chem. Type/Ther. Class:
1S

PHARMACOL.
Peripheral H₁-receptor antagonist for allergic rhinitis (both PAR and SAR).

CATEGORY/INDICATION:
Solid oral dosage form (tablet, film coated)

5 mg. (Total daily dose: 5 mg)

STRENGTHS:

ROUTE OF ADMINISTRATION:
Oral

0 Rx

OTC

YES

NO

DISPENSED:

SPECIAL PRODUCTS:
(If yes, fill out the form for special products and deliver to the TIA through the team leader for data entry)

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

8-Chloro-6,11-dihydro-11-(4-piperidinylidene)-9H-benzo-
[5,6]cyclohepta[1,2-b]pyridine
Molecular Formula: C₉H₁₈ClN₂
Molecular Weight: 310.8
REMINDERS/COMMENTS:

Drug Substance and Drug Product  
(Please see review page 4)  

CONCLUSIONS AND RECOMMENDATIONS:  
The application is approvable from the standpoint of chemistry, manufacturing and controls since a withhold EER was generated dated January 19, 2001 pertaining to N21-165. An EER has been forwarded to OC dated 9/19/00 for the application N21-297 and 4/18/01 for this application N21-363 with the same sites as N21-165. When an acceptable EER for all sites is provided for N21-363 this application may be approved, but not before the approval of N21-165.

cc:  
Orig. NDA 21-363  
HFD-570/Division File N21-363  
HFD-570/KSwiss/5/4/01  
HFD-570/Grout  
HFD-570/GPoochikian  
HFD-820/SSoepke  
HFD-800/CHoiberg  
R/D Init. by:  
filename:  N21363.C1.DOC  

______________________________  
Kevin A. Swiss, Ph.D. Review Chemist
SUPPORTING DOCUMENTS:

DMFs

RELATED DOCUMENTS (if applicable)

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### REMARKS/COMMENTS:

In the BC Amendment dated April 19, 2001 of this NDA 21-363, NDA 21-165 has been referenced for both drug substance and drug product.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
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Kevin Swiss
5/4/01 02:21:42 PM
CHEMIST

Guiragos Poochikian
5/4/01 05:42:41 PM
CHEMIST
Application: NDA 21363/000
Stamp: 10-APR-2001 Regulatory Due: 10-FEB-2002
Applicant: SCHERING
GALLOPING HILL RD
KENILWORTH, NJ 07033

Priority: 1S
Org Code: 570
Action Goal: 
District Goal: 12-DEC-2001
Brand Name: CLARINEX (DESLORATADINE) 5MG TABLETS

Established Name: 
Generic Name: DESLORATADINE
Dosage Form: TAB (TABLET)
Strength: 5 MG

FDA Contacts: ID = 121539
R. NISHIKAWA (HFZ-017), Project Manager
G. POOCHIKIAN (HFD-570), Review Chemist
301-827-1050, Team Leader

Overall Recommendation:
ACCEPTABLE on 31-JAN-2002 by P. LEFLER (HFD-324) 301-827-0062
WITHHOLD on 10-AUG-2001 by B. HARTMAN (HFD-324) 301-827-0067
WITHHOLD on 27-JUL-2001 by LABRADORW

Establishment: 2650155
SCHERING CORP
PRIDCO INDUSTRIAL PARK SR 83
LAS PIEDRAS, PR 00671

DMF No: 21165 021297

Profile: TCM OAI Status: OAI ALERT Responsibilities:
Last Milestone: OC RECOMMENDATION
Milestone Date: 30-JAN-2002
Decision: ACCEPTABLE
Reason: BASED ON FILE REVIEW
FIRM RESPONSE TO DEFIC. ADEQ

Establishment: 9612726
SCHERING PLOUGH (AVONDALE) /
COUNTY WICKLOW, EI

DMF No: 21165 021297

Profile: CSN OAI Status: NONE Responsibilities:
Last Milestone: OC RECOMMENDATION
Milestone Date: 22-JAN-2002
Decision: ACCEPTABLE
Reason: BASED ON PROFILE
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**Application Comment:** THIS IS AN ADDITIONAL MEDICAL INDICATION FOR DESLORATADINE (CLARINEX) 5 MG TABLETS. THE CMC OF THIS NDA IS IDENTICAL TO THAT OF N 21165 AND N 21297. THIS NDA CANNOT BE APPROVED UNTIL N 21165 IS APPROVED. (on 18-APR-2001 by K. SWISS ()

**FDA Contacts:**
- G. TROUT (HFD-570) 301-827-1050, Project Manager
- K. SWISS, Review Chemist
- G. POOCHIKIAN (HFD-570) 301-827-1050, Team Leader

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### Overall Recommendation:

**Establishment: 2211256**

SCHERING CORP
1011 MORRIS AVE
UNION, NJ 07083

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**Establishment: 2650155**

SCHERING CORP
PRIDCO INDUSTRIAL PARK SR 83
LAS PIEDRAS, PR 00671

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**Establishment: 9612726**

SCHERING PLOUGH (AVONDALE) / LOFTUS BRYAN COUNTY WICKLOW, EI

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Establishment: 9614153  
SCHERING PLOUGH CORP  
50 TUAS WEST DR  
SINGAPORE,  SN  638408  

DMF No:  
Responsibilities:  

Profile:  CSN  
OAI Status: NONE  

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APPEARS THIS WAY ON ORIGINAL