

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 2/8/02: 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 and N21-363 of ACCEPTABLE on 1/31/02.*

PK

Orig. NDA 21-297
Orig. NDA 21-363
HFD-570/Div. Files
HFD-570/CBertha 1/24/02
HFD-570/GPoochikian
HFD-570/AZeccola

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/s/

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

Guiragos Poochikian
1/25/02 10:53:47 AM
CHEMIST

REMARKS/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/GTrout
HFD-570/GPoochikian
HFD-820/SKoepe
HFD-800CHOiberg
R/D Init. by: _____
filename: N21363.CR1.DOC

/S/

Kevin A. Swiss, Ph.D. Review Chemist

SUPPORTING DOCUMENTS:

DMFs

RELATED DOCUMENTS (if applicable)

<u>Type</u>	<u>Number</u>	<u>Owner</u>	<u>Subject</u>
IND		Schering Corp.	
IND		Schering Corp.	
IND		Schering Plough	
IND		Schering Plough	
IND		Schering Corp.	
IND		Schering Plough	SCH 34117 Tablets
NDA	19-658	Schering Corp.	Claritin® (Loratadine) 10 mg Tablet
NDA	21-165	Schering Plough	Desloratadine Tablets
NDA	21-297	Schering Plough	Desloratadine Tablets (chronic idiopathic urticaria)
NDA		Schering Plough	
NDA		Schering Plough	

CONSULTS:

CONSULT	DATE FORWARDED	STATUS	COMMENTS
EER	4/18/01	Pending	Pending inspection
Environmental Assessment	Not applicable	Adequate	Applicant has applied for a categorical exclusion under 21 CFR 25.31(b) in NDA.
Methods Validation	11/1/00 for N21-165	Sent, Results are Pending	MV for drug substance (assay, assay related compounds, polymorph content, PSD) and drug product (dissolution rate, moisture, assay, degradation products, uniformity of dosage units)

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.

APPEARS THIS WAY
ON ORIGINAL

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/s/

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

Guiragos Poochikian
5/4/01 05:42:41 PM
CHEMIST

**ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Application: NDA 21363/000	Priority: 1S	Org Code: 570
Stamp: 10-APR-2001 Regulatory Due: 10-FEB-2002	Action Goal:	District Goal: 12-DEC-2001
Applicant: SCHERING	Brand Name: CLARINEX (DESLORATADINE) 5MG	TABLETS
GALLOPING HILL RD	Established Name:	
KENILWORTH, NJ 07033	Generic Name: DESLORATADINE	
	Dosage Form: TAB (TABLET)	
	Strength: 5 MG	
FDA Contacts: ID = 121539		, Project Manager
R. NISHIKAWA (HFZ-017)		, Review Chemist
G. POOCHIKIAN (HFD-570)	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	DMF No:
SCHERING CORP	AADA No: 021165 021297
PRIDCO INDUSTRIAL PARK SR 83	
LAS PIEDRAS, PR 00671	

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	DMF No:
SCHERING PLOUGH (AVONDALE) /	AADA No: 021165 021297
COUNTY WICKLOW, , EI	

Profile: CSN	OAI Status: NONE	Responsibilities:
Last Milestone: OC RECOMMENDATION		
Milestone Date: 22-JAN-2002		
Decision: ACCEPTABLE		
Reason: BASED ON PROFILE		

Application: NDA 21363/000
Stamp: 10-APR-2001
Regulatory Due: 10-FEB-2002
Applicant: SCHERING
GALLOPING HILL RD
KENILWORTH, NJ 07033

Action Goal:
District Goal: 12-DEC-2001
Brand Name: CLARINEX (DESLORATADINE) 5MG TABLETS
Estab. Name:
Generic Name: DESLORATADINE

Priority:
Org Code: 570

Dosage Form: (TABLET)
Strength: 5 MG

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

Overall Recommendation:

Establishment: 2211256
SCHERING CORP
1011 MORRIS AVE
UNION, NJ 07083

DMF No: AADA: 021165 021297

Responsibilities:

Profile: TCM OAI Status: NONE

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	18-APR-2001				SWISSK

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

DMF No: AADA: 021165 021297

Responsibilities:

Profile: TCM OAI Status: POTENTIAL OAI

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	18-APR-2001				SWISSK

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

DMF No: AADA: 021165 021297

Responsibilities:

Profile: CSN OAI Status: NONE

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	18-APR-2001				SWISSK

Establishment: 9614153

SCHERING PLOUGH CORP
50 TUAS WEST DR
SINGAPORE, , SN 638408

DMF No:

AADA: 021165 021297

Responsibilities:

Profile: CSN

OAI Status: NONE

Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	18-APR-2001				SWISSK

**APPEARS THIS WAY
ON ORIGINAL**