CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-312

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-312

DISCIPLINE REVIEW LETTER

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Nicholas J. Pelliccione, Ph.D.
Vice President, CMC
Worldwide Regulatory Affairs

Dear Dr. Pelliccione:

Please refer to your December 21, 2000 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex RediTabs (5 mg desloratadine orally disintegrating tablets).

We also refer to your submissions dated May 22 and July 19, 2001.

Our review of the Chemistry, Manufacturing and Controls section of your submission is complete, and we have identified the following deficiencies.

1.

2.

3.

4. The following comments pertain to the labels and/or labeling.

   a. It is recommended that the labeling on the unit-of-use individual foil-foil blister units for the Clarinex RediTabs appear distinctly different (e.g., use of contrasting colors) from that for the Claritin RediTabs product.

   b. The dosage form descriptor should be changed from "rapidly-disintegrating tablet" to "orally disintegrating tablet."

c. The established name "desloratadine orally distintegrating tablets" should have a prominence commensurate with the prominence with which the proprietary name appears, taking into consideration all pertinent factors (typography, layout, contrast, and other printing features).

d. Clarify the location of the lot number and expiration date for the cartons.

e. Additional comments on labels and labeling may be forthcoming.

5. Submit four copies of a method validation package that contain the drug substance and drug product methods, associated validation data, a list of drug product, drug substance and associated samples, and the certificates of analysis for the corresponding samples.

6. Comments may be forthcoming regarding your proposed 24-month expiration dating period for the product, once the available stability data are statistically analyzed versus the shelf-life acceptance criteria.

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

If you have any questions, call Mr. David Hilfiker, Regulatory Project Manager, at (301) 827-1084.

Sincerely yours,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC 2, Office of New Drug Chemistry
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Alan Schroeder
8/14/01 11:07:15 AM
Signed for Guirag Poochikian, Ph.D.

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-312

DISCIPLINE REVIEW LETTER

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Joseph F. Lamendola, Ph.D.
Vice President
US Regulatory Affairs

Dear Dr. Lamendola:

Please refer to your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clarinex (desloratadine) Reditabs.

We also refer to your submission dated March 26, 2001.

Our review of the Chemistry, Manufacturing and Controls section of your submission is complete, and we have identified the following deficiencies:

1. [redacted]
2.
3.
4.
5.

6. [redacted]

7.

8.

9.

10.

11

12.

13.

14. The following preliminary comments pertain to the labels and labeling.

a. In the HOW SUPPLIED section of the labeling and on the labels, the recommended storage temperature and range for excursion should also be given in Fahrenheit, and reference should be made to "see USP Controlled Room Temperature."

b. Before complete comments on labeling of the drug product can be given, please submit label (color) and labeling mock-ups.

c. Indicate in the HOW SUPPLIED section of the labeling that the dosage units are pink in color.

We are providing these comments to you before we complete our review of the entire application to give you preliminary notice of issues that we have identified. In conformance with the prescription drug user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and subject to change as we finalize our review of your application. In addition, we may identify other information that must be provided before we can approve this application. If you respond to these issues during this review cycle, depending on the timing of your response, and in conformance with the user fee reauthorization agreements, we may not be able to consider your response before we take an action on your application during this review cycle.

If you have any questions, call Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

{See appended electronic signature page}

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

/s/

Guiragos Poochikian
4/12/01 11:12:11 AM

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: March 31, 2003
See OMB Statement on page 2.

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Schering Corporation	June 26, 2002
TELEPHONE NO. *(Include Area Code)*	**FACSIMILE (FAX) Number** *(Include Area Code)*
(908) 740-2628	(908) 740-4131
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):*	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* **IF APPLICABLE**
2000 Galloping Hill Road Kenilworth, New Jersey 07033	Joseph F. Lamendola, Ph.D. Vice President, Worldwide Regulatory Affairs 2000 Galloping Hill Road Kenilworth, NJ 07033

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER *(If previously issued)* NDA 21-312

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
orally-disintegrating tablets	CLARINEX® Reditabs Tablets

CHEMICAL/BIOCHEMICAL /BLOOD PRODUCT NAME *(If any)*
8-chloro-6, 11-dihydro-11(4-piperidinylidene)-5H-benzo-[5,6]cyclohepta[1,2-b]pyridine

CODE NAME *(If any)*: SCH 34117

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
RediTab Tablet	5 mg	Oral

(PROPOSED) INDICATION(S) FOR USE:
Seasonal Allergic Rhinitis and Chronic Idiopathic Urticaria

APPLICATION INFORMATION

APPLICATION TYPE (check one)
☐ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94)
☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☒ 505 (b) (1) ☐ 505 (b) (2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION
Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION *(check one)*
☐ ORIGINAL APPLICATION ☐ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION
☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT
☐ LABELING SUPPLEMENT ☐ CHEMISTRY, MANUFACTURING, AND CONTROLS SUPPLEMENT ☒ OTHER

IF A SUBMISSION OR PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Final Draft Labeling

PROPOSED MARKETING STATUS (check one) ☒ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED — THIS APPLICATION IS ☐ PAPER ☒ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided in the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability/testing) conducted at the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

This application contains the following items: *(Check all that apply)*		Paper	Electronic
☒	1. Index	☐	☒
☒	2. Labeling (check one) ☒ Draft Labeling ☐ Final Printed Labeling	☒	☒
☐	3. Summary (21 CFR 314.50 (c))	☐	☐
☐	4. Chemistry section	☐	☐
☐	A. Chemistry, manufacturing, and controls information (e.g. 21 CFR 314.50 (d) (1), 21 CFR 601.2)	☐	☐
☐	B. Samples (21 CFR 314.50 (e) (1), 21 CFR 601.2 (a)) (Submit only upon FDA's request)	☐	☐
☐	C. Methods validation package (e.g. 21 CFR 314.50 (e) (2) (i), 21 CFR 601.2)	☐	☐
☐	5. Nonclinical pharmacology and toxicology section (e.g. 21 CFR 314.50 (d) (2), 21 CFR 601.2)	☐	☐
☐	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)	☐	☐
☐	7. Clinical Microbiology (e.g. 21 CFR 314.50 (d) (4))	☐	☐
☐	8. Clinical data section (e.g. 21 CFR 314.50 (d) (5), 21 CFR 601.2)	☐	☐
☐	9. Safety update report (e.g. 21 CFR 314.50 (d) (5) (vi) (b), 21 CFR 601.2)	☐	☐
☐	10. Statistical section (e.g. 21 CFR 314.50 (d) (6), 21 CFR 601.2)	☐	☐
☐	11. Case report tabulations (e.g. 21 CFR 314.50 (f) (1), 21 CFR 601.2)	☐	☐
☐	12. Case reports forms (e.g. 21 CFR 314.50 (f) (2), 21 CFR 601.2)	☐	☐
☐	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))	☐	☐
☐	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))	☐	☐
☐	15. Establishment description (21 CFR Part 600, if applicable)	☐	☐
☐	16. Debarment certification (FD&C Act 306 (k) (1))	☐	☐
☐	17. Field copy certification (21 CFR 314.5 (k) (3))	☒	☐
☐	18. User Fee Cover Sheet (Form FDA 3397)	☐	☐
☐	19. Financial Information (21 CFR Part 54)	☐	☐
☐	20. OTHER *(Specify)*	☐	☐

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210 and 211, or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Part 201, 606, 610, 660 and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR 202.
5. Regulations on making changes in application in FD&C Act Section 506A, 21 CFR 314.71, 314.72 , 314.97, 314.99, and 601.12.
6. Regulations on Reports in 21 CFR 314.80, 314.81, 600.80 and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information in this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: **A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.**

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
/for Dr. Lamendola	Joseph F. Lamendola, Ph.D. Vice President, Worldwide Regulatory Affairs	06/26/02

ADDRESS *(Street, City, State, and ZIP Code)*	Telephone Number
2000 Galloping Hill Road, Kenilworth, NJ 07033	(908) 740-2628

Public reporting burden for this collection of information is estimated to average 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CSER, HFM-99
1401 Rockville Pike
Rockville, MD 20852-1448

An agency may not conduct or sponsor, and a Person is not required to respond to, a collection of Information unless it displays a currently valid OMB Control Number

WITHHOLD 35 PAGE (S)

Draft

Labeling

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division Office)*: HFD-400/OPDRA/Assoc. Director for Medication Error Prevention

FROM: HFD-570/DPADP/Hilfiker

DATE:	IND NO.:	NDA NO.:	TYPE OF DOCUMENT:	DATE OF DOCUMENT:
July 31, 2001		21-312	CMC amendment	July 19, 2001

NAME OF DRUG:	PRIORITY CONSIDERATION:	CLASSIFICATION OF DRUG:	DESIRED COMPLETION DATE:
Clarinex Reditabs	standard	3S	October 1, 2001

NAME OF FIRM: Schering Corporation

REASON FOR REQUEST

I. GENERAL

☐ NEW PROTOCOL
☐ PROGRESS REPORT
☐ NEW CORRESPONDENCE
☐ DRUG ADVERTISING
☐ ADVERSE REACTION REPORT
☐ MANUFACTURING CHANGE/ADDITION
☐ MEETING PLANNED BY
☐ PRE--NDA MEETING
☐ END OF PHASE II MEETING
☐ RESUBMISSION
☐ SAFETY/EFFICACY
☐ PAPER NDA
☐ CONTROL SUPPLEMENT
☐ RESPONSE TO DEFICIENCY LETTER
☐ FINAL PRINTED LABELING
☐ LABELING REVISION
☐ ORIGINAL NEW CORRESPONDENCE
☐ FORMULATIVE REVIEW
☒ OTHER *(SPECIFY BELOW)*:
Tradename Consult

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES PROTOCOL REVIEW ☐ OTHER:	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER:

III. BIOPHARMACEUTICS

☐ DISSOLUTION
☐ BIOAVAILABILTY STUDIES
☐ PHASE IV STUDIES
☐ DEFICIENCY LETTER RESPONSE
☐ PROTOCOL-BIOPHARMACEUTICS
☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
☐ SUMMARY OF ADVERSE EXPERIENCE
☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: Please provide comments on the proposed carton mock-ups (attached) bearing the tradename Clarinex Reditabs. Specifically, we would like to know if OPDRA has any reservations about the artwork on the cartons and graphical expression of the tradename and whether that may lead to medication errors.

Attachments: Proposed sample and 30-unit cartons for Clarinex Reditabs (provided in the 7-19-01 amendment to NDA 21-312)

SIGNATURE OF REQUESTER:	METHOD OF DELIVERY (Check one): ☒ MAIL ☐ HAND

C:\my_documents\N21312\010731namecon

WITHHOLD 2 PAGE (S)

Draft

Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

David Hilfiker
7/31/01 11:30:15 AM

APPEARS THIS WAY
ON ORIGINAL

DUPLICATE

SCHERING CORPORATION

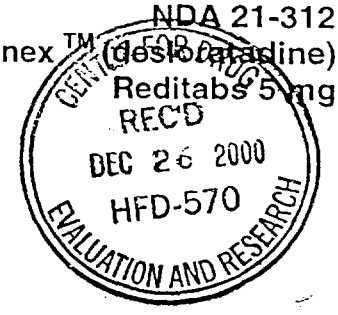
2000 GALLOPING HILL ROAD KENILWORTH, N.J. 07033

TELEPHONE: (908) 298-4000

December 20, 2000

Robert Meyer, M.D., Director
Division of Pulmonary & Allergy Drug Products
Center for Drug Evaluation and Research
HFD-570, Room 10B03
5600 Fishers Lane
Rockville, MD 20857

NDA 21-312
Clarinex™ (desloratadine)
Reditabs 5 mg



SUBJECT: ORIGINAL NEW DRUG APPLICATION

Dear Dr. Meyer:

In accordance with 21 CFR 314.50, submitted is an original New Drug Application for Clarinex ™ Reditabs 5 mg tablets for the treatment of seasonal allergic rhinitis and chronic idiopathic urticaria. Desloratadine is an active metabolite of loratadine, and is the subject of the following [redacted] NDA 21-165 for seasonal allergic rhinitis, NDA 21-297 for chronic idiopathic urticaria, [redacted]

This application includes pharmacokinetic data from two phase I trials which showed the safety and tolerance of Reditabs. The first study demonstrated bioequivalence of the Reditab to both the tablet and [redacted] formulations. The second study demonstrated that food and water had no effect on the bioavailability of desloratadine and 3-hydroxy desloratadine from the Reditab formulation.

The content and format of this application were discussed with the Division of Pulmonary and Allergy Drug Products at the January 18, 2000 pre-NDA meeting. It was agreed that our clinical pharmacology program was acceptable. This NDA is being submitted in a similar electronic format to the Clarinex Tablet NDA submission, as requested by the Agency.

As requested by the Agency during a January 18, 2000 Pre-NDA meeting, we have provided with the [redacted]) a "Global" Integrated Safety Summary which incorporates safety data from all clinically complete (as of June 1, 2000) studies that utilized desloratadine. Please refer to Section 20 of that

Chemistry, Manufacturing and Controls issues for this product were also discussed at the pre-NDA meeting. As accepted by the Division, please cross reference NDA 21-165 for all drug substance information. Also, as requested by the Division at the pre-NDA meeting, we have included the drug substance specifications in this NDA and have submitted consolidated updated drug substance sections to NDA 21-165. This was originally submitted on June 29, 2000, and updated on August 2 and September 14, 2000. The influence of environmental factors on the color of the product is addressed in section 4.B.6. of this NDA.

As provided in both the ICH QIA Guidance (September,1994) and the FDA Draft Guideline (June, 1998) both entitled, "Stability Testing of Drug Substance and Drug Products", because the product exhibited excellent stability, we did not perform the regression analysis. Thus, there are no electronic files in SAS for the stability data. Please refer to section 4.B.8. for stability data.

Regarding a degradation product in this product, we refer you to our pre-NDA meeting held January 18, 2000 and a telephone conversation held on March 28, 2000 between Dr. Poochikian of your division and Dr. Pelliccione of Schering. At the pre-NDA meeting the Agency provided direction that degradation products could be within the ICH guideline qualification and identification threshold limits unless they were identified as ——— which were to be held below — or qualified by toxicology studies. During that meeting we had identified a degradant as potentially being an —— Subsequent analytical work determined that this compund is a ——————————— and therefore did not constitute a structural alert. Based on that information, the March 28, 2000 call to Dr. Poochikian took place in which this information was conveyed. Dr. Poochikian said that we should provide a summary of our finding to the IND prior to the NDA filing. In an August 31, 2000 amendment to IND ——— serial number 013), we submitted the summary of the analyzed work done to verify the structure of the compound and also included a summary of our toxicological assessment, which determined this compound does not constitute a structural alert.

Also, as agreed to by the Agency, the preclinical sections of this NDA are cross referenced to the Tablet NDA (21-165), with the exception of a mucous membrane irritation study in the hamster cheek pouch (found in section 5 of this NDA).

A summary of meetings with the Agency delineating additional agreements can be found in Section 8B (Background/Overview of Clinical Investigations), Part 4 (FDA Meetings/Communications).

Labeling is included in this submission in sections 2 and 3A. This version of the labeling encompasses those latest revisions requested of the original Tablet labeling on November 14, 2000.

In accordance with 21 CFR Part 54, FDA Form 3454 is included with this submission, which certifies that Schering did not participate in any financial arrangement with any clinical investigator whereby the value of the compensation could be affected by the outcome of the study or acted in due diligence to obtain the

information required under 54.4. Form 3454 is included in section 19 of this application.

Claim for Exclusivity In accordance with the provisions of Sections 505 (c) (3) (D) (iii) and 505 (j) (4) (D) (iii) of the Food, Drug and Cosmetic Act and 21 CFR 314.108 (b) (4), exclusivity is claimed for this product. Information in support of the claim for exclusivity is provided in Section 20 of this application.

Debarment Certification In accordance Section 306(k) of the Food, Drug and Cosmetic Act, Schering Corporation certifies that, with respect to this application, it did not and will not knowingly use the services of any persons that have been debarred under the provisions of Section 306 (a) or (b) of the Act.

Field Copy Certification As requested by the New Jersey Division, we are providing a copy of this cover letter only to the District since the manufacturing location of this product is in a foreign country.

Pediatric Use In accordance with 21 CFR Part 314.55, Schering hereby submits our pediatric plans. (Note: Please see section 20 of this NDA for a complete summary of our pediatric plans). [ ] Therefore, we are requesting a deferral of pediatric studies for this age group with this submission.

For subjects ≤ 2 years of age, we are requesting a waiver for this age group. ———

Attached to this letter are deferral and waiver requests consistent with the Agency's November 27, 2000 Draft Guidance for Industry entitled, "Recommendations for Complying with the Pediatric Rule (21 CFR 314.55 (a) and 601.27 (a))."

User Fee A check in the amount of ——— was sent to FDA's designated Pittsburgh location on October 2, 2000. This check represented the estimated user fee amount for the current fiscal user as provided by FDA. The User Fee Cover Sheet (User Fee ID No. 4024) is included with this submission.

Electronic Format-NDA The submission is being provided in hardcopy and electronic format. We have followed the guidance, "Providing Regulatory Submissions in Electronic-Format-NDA's" issued in January of 1999. The electronic portion of the submission is divided into two sections. The first section contains read only files consisting of reports, summaries, etc., and is presented in portable document format (pdf). The second section consists of the data portion, presented in SAS Transport file format. A Microsoft ® Word version of the labeling is also being provided.

Please be advised that the material and data contained in this submission are considered to be confidential. The legal protection of such confidential commercial material is claimed under the applicable provisions of 18 U.S.C., Section 1905 or 21 U.S.C., Section 331(j) as well as the FDA

Sincerely,

Joseph F. Lamendola, Ph.D.
Vice President
U.S. Regulatory Affairs

BK/js

APPEARS THIS WAY
ON ORIGINAL

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application : NDA 21312/000
Org Code : 570
Priority : 3S

Sponsor: SCHERING
2000 GALLOPING HILL RD
KENILWORTH, NJ 070335030

Stamp Date : 21-DEC-2000
PDUFA Date : 26-JUN-2002
Action Goal :
District Goal: 27-APR-2002

Brand Name : CLARINEX (DESLORATADINE) REDITABS 5MG
Estab. Name:
Generic Name: DESLORATADINE
Dosage Form: (TABLET)
Strength : 5 MG

FDA Contacts: ID = 121539 Project Manager
C. BERTHA Review Chemist (HFD-570) 301-827-1050
G. POOCHIKIAN Team Leader (HFD-570) 301-827-1050

Overall Recommendation: ACCEPTABLE on 26-JUN-2002by P. LEFLER(HFD-324) 301-827-0062
WITHHOLD on 10-AUG-2001by B. HARTMAN(HFD-324) 301-827-0067

Establishment : CFN : [redacted] FEI : [redacted]

DMF No: AADA:

Responsibilities: [redacted]

Profile : TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 04-JUN-02
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : 1010370 FEI : 1010370
SCHERING CORP
13900 NW 57TH CT
MIAMI LAKES, FL 33014

DMF No: AADA:

Responsibilities: FINISHED DOSAGE PACKAGER

Profile : TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-JUN-02
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : 2210048 FEI : 2210048
SCHERING CORP
2000 GALLOPING HILL RD
KENILWORTH, NJ 07033

DMF No: AADA:

Responsibilities: FINISHED DOSAGE PACKAGER

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Profile : TCM OAI Status: POTENTIAL OAI
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-JUN-02
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

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

DMF No: AADA:

Responsibilities: FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Profile : CTL OAI Status: POTENTIAL OAI
Last Milestone: OC RECOMMENDATION
Milestone Date: 26-JUN-02
Decision : ACCEPTABLE
Reason : BASED ON FILE REVIEW

APPEARS THIS WAY
ON ORIGINAL

BEST POSSIBLE COPY

ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

BASED ON PROFILE

Establishment : CFN : 9612726 FEI : 3002806435
SCHERING PLOUGH (AVONDALE) / LOFTUS BRYAN
COUNTY WICKLOW, , EI

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

Profile : CSN OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 04-JUN-02
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO: (Division/Office)	FROM:
Steve Wilson, Biometrics, HFD-715	Craig M. Bertha, HFD-570

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
7/30/01		21-312	NDA Amendment	7/19/01

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
CLARINEX REDITABS (desloratadine rapidly-disintegrating tablets)	3	S	9/30/01

NAME OF FIRM: Schering-Plough, Inc.

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY _____
- ☐ PRE-NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- X OTHER *(Specify below)*

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER	X CHEMISTRY ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABLITY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ *IN-VIVO* WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS *(List below)*
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS: **Please evaluate the appropriateness of the proposed 24 month expiry period for the drug product based on the 18 month stability data collected on the three batches of product stored under conditions of 25°C/60%RH for the parameters of *assay, moisture content, tensile strength, and dissolution at the 4 minute sampling interval.* The applicant appears to have provided SAS data files on a disk but the hardcopy in tabular form is also included with this consult request. Batches of drug product are 22489F532S, 22489F533S abd 22489F548S.**

cc: Orig NDA 21-312
HFD-570/Div File
HFD-570/CBertha
HFD-570/DHilfiker/SBarnes

SIGNATURE OF REQUESTER	METHOD OF DELIVERY *(Check one)* ☐ MAIL X HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Guiragos Poochikian
7/30/01 12:17:50 PM

APPEARS THIS WAY
ON ORIGINAL