CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

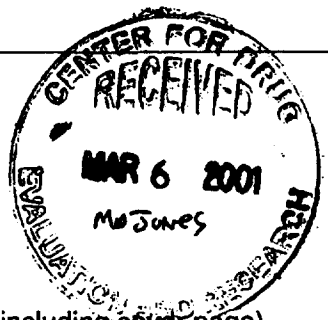
APPLICATION NUMBER
21-363

Correspondence

Schering-Plough Research Institute

2015 Galloping Hill Road
Kenilworth, New Jersey 07033

TELECOPIER TRANSMITTAL SHEET



Please deliver the following 3 pages (including cover page)

If transmittal is incomplete or illegible, please call: Daniel McHugh at 908-740-6744

DATE:	March 06, 2001
TO:	Mike Jones
FAX NUMBER:	301-827-5562

FROM:	Daniel McHugh
LOCATION:	K-6-1
FAX NUMBER:	908-740-6744
SUBJECT:	USER FEE 4110 for CLARINEX NDA 21363

MESSAGE:

Mike-
Attached is the user fee cover sheet (FORM FDA 3397) for the CLARINEX Tablet Allergic Rhinitis NDA which will be submitted to the Pulmonary Division during April 2001. The NDA number is 21363 and the user fee number is 4110. As discussed, monies associated with user fee 4062 ($142,870.00) and user fee 4086 ($154,823.00), which were previously submitted, will be used for this NDA. The difference in the user fee rate for FY 2001 ($11,954.00) will be sent to the Mellon Client Service Center shortly. This will bring the total to $309,674.00 ($142,870.00 + $154,823.00 + $11,954.00).

If you have any further questions please call Daniel McHugh at 908-740-6744 or Mary Jane Boyle at 908-740-5693.

Sincerely,

Daniel McHugh

Cc: Gretchen Trout
Fax 301-827-1271

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

Form Approved: OMB No. 0910-0297
Expiration Date: 04-30-01

USER FEE COVER SHEET

See Instructions on Reverse Side Before Completing This Form

1. APPLICANT'S NAME AND ADDRESS

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attn: Joseph F. Lamendola, Ph.D.

2. TELEPHONE NUMBER (*Include Area Code*)
(908) 740-2628

3. PRODUCT NAME
CLARINEX (desloratadine) Tablet

4. DOES THIS APPLICATION REQUIRE CLINICAL DATA FOR APPROVAL? IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

IF RESPONSE IS 'YES', CHECK THE APPROPRIATE RESPONSE BELOW:

☒ THE REQUIRED CLINICAL DATA ARE CONTAINED IN THE APPLICATION.

☐ THE REQUIRED CLINICAL DATA ARE SUBMITTED BY REFERENCE TO ___ (APPLICATION NO. CONTAINING THE DATA).

5. USER FEE I.D. NUMBER
4110

6. LICENSE NUMBER / NDA NUMBER
NDA 21-363

7. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT BEFORE 9/1/92 (*Self Explanatory*)

☐ A 505(b)(2) APPLICATION THAT DOES NOT REQUIRE A FEE (*See item 7, reverse side before checking box.*)

☐ THE APPLICATION QUALIFIES FOR THE ORPHAN EXCEPTION UNDER SECTION 736(a)(1)(E) of the Federal Food, Drug, and Cosmetic Act (*See item 7, reverse side before checking box.*)

☐ THE APPLICATION IS A PEDIATRIC SUPPLEMENT THAT QUALIFIES FOR THE EXCEPTION UNDER SECTION 736(a)(1)(F) of the Federal Food, Drug, and Cosmetic Act (*See item 7, reverse side before checking box.*)

☐ THE APPLICATION IS SUBMITTED BY A STATE OR FEDERAL GOVERNMENT ENTITY FOR A DRUG THAT IS NOT DISTRIBUTED COMMERCIALLY (*Self Explanatory*)

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ AN APPLICATION FOR A BIOLOGICAL PRODUCT FOR FURTHER MANUFACTURING USE ONLY

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGICAL PRODUCT LICENSED UNDER SECTION 351 OF THE PHS ACT

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

8. HAS A WAIVER OF AN APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION?

☐ YES ☒ NO

(*See reverse side if answered YES*)

A completed form must be signed and accompany each new drug or biologic product application and each new supplement. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment.

Public reporting burden for this collection of information is estimated to average 30 minutes 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:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0297)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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.*

Please DO NOT RETURN this form to this address.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
/for Dr. Lamendola	Vice President U.S. Regulatory Affairs	3/6/01

FORM FDA 3397 (5/98)

****
THE FOOD AND DRUG ADMINISTRATION
* USER FEE ID ASSIGNMENT SYSTEM *
****

****** SUBMISSION INFORMATION ******

APPLICATION: N021363

ORIGINAL OR SUPPLEMENT: N

RESUBMISSION?:

FAX NUMBER: 9087406500

COMPANY: SCHERING-PLOUGH CORP.

REQUEST DATE: 06-MAR-2001

---------->> USER FEE ID#: 4110

The assigned User Fee ID number must be noted on the submission sent into the FDA for review and also noted on the submitted payment.

This FAX will be the only notification you will receive of this User Fee ID Assignment.

Electronic Mail Message

Date: 03/06/2001 2:33:06 PM
From: Michael Jones (JONESM)
To: See Below
Subject: New NDA 21363 for Clarienx

Ladies,

Schering had planned on submitting two supplments to their pending NDA for Clarinex (NDA 21165). They submitted the following fees:

NDA 21165, UF ID # 4062, $142,870 on 12/26/2000
NDA 21165, UF ID # 4086, $154,823 on 2/15/2001

Becuase the application was not approved they are going to submit a NEW NDA and they will pay for the new NDA by using the fees noted above. In addtion, they plan on submitting another $11,954 under UF ID number 4110.

So ... when the payment comes in - in a week or so. Please change our records to show that a total of $309,647 came in for NDA 21363 under her fee ID number 4110.

If you have any questions or if you anticpate any problems please let me know.

Thanks

Mike

PS: See attached fax from Schering.

To: SHARRON D BUTLER (OC) (SBUTLER@OC.FDA.GOV)
To: DONNA E SIMMS (OC) (DSIMMS@OC.FDA.GOV)
To: SUSAN D FARRAN (OC) (SFARRAN@OC.FDA.GOV)
To: Fran Rowland (ROWLAND)
To: Gretchen Trout (TROUTG)
Cc: Beverly Friedman (FRIEDMANB)
Cc: Tawni Brice (BRICET)

Schering-Plough Research Institute

2000 Galloping Hill Road
Kenilworth, New Jersey 07033

TELECOPIER TRANSMITTAL SHEET

Please deliver the following 3 pages (including cover page)

If transmittal is incomplete or illegible, please call: Daniel McHugh at 908-740-6744

[redacted]	February 07, 2002
	Anthony Zeccola
	301-827-1271

[redacted]	Daniel McHugh
	Debarment Cerification

[redacted]

Tony-

Here is the debarment certification for NDA 21-363. The same text appeared in the cover letter for NDA 21-297 so I am sending you a clarification for that NDA also.

Dan

SCHERING CORPORATION

2000 GALLOPING HILL ROAD KENILWORTH, N.J. 07033

TELEPHONE: (908) 298-4000

February 7, 2002

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 21-363
CLARINEX® Tablets
(desloratadine)
Allergic Rhinitis

SUBJECT: GENERAL CORRESPONDENCE

Dear Dr. Meyer:

As discussed with Mr. Zeccola and Ms. Barnes on February 7, 2002, the correct "debarment certification" for this NDA appears in Section 16, page one. To reiterate,

> Schering Corporation hereby certifies that it did not and will not use in any capacity the services of any person debarred under section 306 of the Federal Food, Drug and Cosmetic Act in connection with this application.

If there are any questions in regards to this matter, please contact Daniel McHugh at (908) 740-6744 or Mary Jane Boyle at (908) 740-5693.

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

****
*** TX REPORT ***
****

TRANSMISSION OK

TX/RX NO	1336
CONNECTION TEL	919087406744
SUB-ADDRESS	
CONNECTION ID	SCHERING PLOUGH
ST. TIME	01/31 09:15
USAGE T	02'22
PGS.	16
RESULT	OK

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF DRUG EVALUATION II

Division of Pulmonary and Allergy Drug Products

Parklawn Building, Room 10B-45
5600 Fishers Lane HFD – 570
Rockville, MD 20857

To:

Name: Daniel McHugh

Organization Name/Dept:

CC:

Phone number:

Fax number: 908-740-0744

From: Tony Beccola

FAX: 301 – 827 – 1271

Phone: 301 – 827 – 1050

- ☐ Urgent
- ☐ For Review
- ☐ Please Comment
- ☐ Please Reply
- ☐ OTHER:

Date sent: 1/31/01

Number of pages including cover page: 16

Message: Dan,
Here are the suggested changes. Please note me where there are "X's, you will need to fill in the information

15 pages redacted from this section of the approval package consisted of draft labeling