CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
21-297

Correspondence

SCHERING CORPORATION

2000 GALLOPING HILL ROAD KENILWORTH, N.J. 07033

TELEPHONE: (908) 298-4000

February 6, 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 21-297
CLARINEX® Tablets
(desloratadine)
CIU

SUBJECT: FINAL DRAFT LABELING

Dear Dr. Meyer:

Reference is made to a facsimile dated February 4, 2002, containing labeling changes for NDA 21-297. We have accepted the FDA's revised text, and as we discussed on February 6, 2002, we have added a new "Table 4" containing the pruritus symptom scores for CLARINEX Tablet and placebo.

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

DM:js
Enclosure

Desk copy: Central Document Room (electronic file room.pdf files)

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

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

TRANSMISSION OK

TX/RX NO	1347
CONNECTION TEL	919087404131
SUB-ADDRESS	
CONNECTION ID	SPRI INST WORLDW
ST. TIME	02/04 16:40
USAGE T	02'12
PGS.	15
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: Dan McHugh

Organization Name/Dept:

CC:

Phone number:

Fax number: 908 - 740 4131

From: Tony Zeccola

FAX: 301 – 827 – 1271

Phone: 301 – 827 – 1050

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

Date sent: 2/4/01

Number of pages including cover page: 15

Message: Working DAP - CIU

NDA ACKNOWLEDGEMENT LETTER

September 15, 2000

NDA 21-297

SEP 18 2000

Schering Corporation
2000 Galloping Hill Road
Kenilworth, New Jersey 07033-0530

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

Dear Dr. Lamendola:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Clarinex (desloratadine 5 mg) Tablets

Review Priority Classification: Standard (S)

Date of Application: August 30, 2000

Date of Receipt: August 31, 2000

Our Reference Number: NDA 21-297

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on October 30, 2000, in accordance with 21 CFR 314.101(a). If the application is filed, the primary user fee goal date will be June 30, 2001 and the secondary user fee goal date will be August 31, 2001.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). If you have not already fulfilled the requirements of 21 CFR 314.55 (or 601.27), please submit your plans for pediatric drug development within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will make a determination whether to grant or deny a request for a waiver of pediatric studies during the review of the application. In no case, however, will the determination be made later than the date action is taken on the application. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application. All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Drug Products, HFD-570
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

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

Sincerely,

/S/

Sandy Barnes
Chief, Project Management Staff
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDA 21-297
HFD-570/Div. Files
HFD-570/Trout
DISTRICT OFFICE

Drafted by: pj/September 11, 2000
Initialed by: sbarnes/9-13-00
final:pj/9-15-00
filename: N21297.AKN

ACKNOWLEDGEMENT (AC)