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APPLICATION NUMBER: NDA 20233/S003

CORRESPONDENCE

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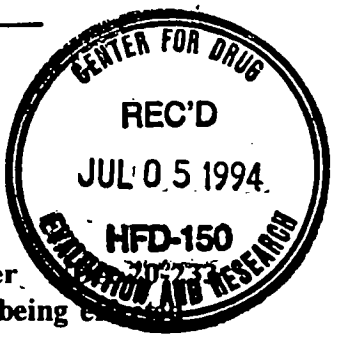
July 1, 1994

NDA NO. 20 233 REF. NO. 001

NDA SUPPL FOR SUB



Gregory Burke, M.D., Director
Division of Oncology and Pulmonary
Drug Products (HFD-150)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-1706

RE: Rhinocort® Nasal Inhaler
Supplement 1: Changes being
Final Printed Labeling

Dear Dr. Burke:

Reference is made to the recently approved final printed labeling for Rhinocort Nasal Inhaler, NDA 20-233, and to the Patient's Instructions For Use which appear at the bottom of the package insert and on the product package. An inconsistency between these instructions and the package insert Dosage and Administration directions has been discovered. The intent of this supplement is to correct this discrepancy.

The first sentence in Dosage and Administration states "Adults and children 6 years of age and older: The recommended starting dose is 256 µg daily, given as either two sprays in each nostril morning and evening or as four sprays in each nostril in the morning."

In the second paragraph under "N.B." of the Patient's Instructions for Use the last sentence reads
This statement is inconsistent with the once daily dosing alternative described under Dosing and Administration.

We, therefore, propose to change the wording of this sentence in the Patient's Instructions to eliminating the words

Please find enclosed a revised package insert (Attachment 1), a mock-up of the revised package (Attachment 2) and a copy of the original package insert for reference (Attachment 3). The statements that have been revised are highlighted.

If you have any questions regarding this submission, please contact me at (508) 366-1100, Extension 4793.

Sincerely yours,

Larry Paglia

Larry M. Paglia, Ph.D.
Director, Regulatory Affairs

Attachments

MAILING ADDRESS:
Astra USA, Inc.
P.O. Box 4500
Westborough, MA 01581-4500

OFFICE:
50 Otis Street
Westborough, MA

TEL:
508 366-1100

FAX:
508 366-7406
TELEX:
6810105-Cable/Astrapharm