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APPLICATION NUMBER:NDA 20233/S003

ADMINISTRATIVE DOCUMENTS

JAN 29 1996

Consumer Safety Officer Review

NDA 20-233/S-001 and S-003

Sponsor: Astra USA

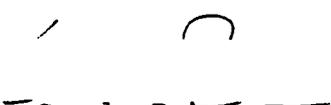
Drug: Rhinocort Nasal Inhaler

Dates of supplements: S-001 July 1, 1994
S-003 August 17, 1995

These supplemental applications provide for changes to the labeling as follows.

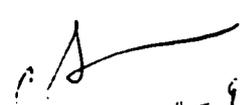
- S-001 - a revision to the Patient's Instructions to correct a discrepancy between the Patient's Instructions and Dosage and Administration section. Specifically the statement
- was changed to "It is therefore very important that Rhinocort is used regularly" to reflect the once daily dosing alternative.
- S-003 - A revision to the Patient's Instructions to ensure proper use of the inhaler.

No additional changes were noted in a comparison to the currently approved labeling. S-001 should be acknowledged and retain and S-003 should be approved.


Sandy Barnes
Consumer Safety Officer

cc:OrigNDA 20-233/S001 and S-003
DivFile
HFD-570/SBarnes1/27/96
HFD-570/BOtulana

N20233S3.rev


1-29-96