CENTER FOR DRUG EVALUATION AND RESEARCH

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

1-29-96

N20233S3.rev