CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-441/S001

Trade Name: Pulmicort Turbuhaler

Generic Name: budesonide inhalation powder, 200 mcg

Sponsor: Astra Pharmaceuticals

Approval Date: February 13, 1998

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APPLICATION NUMBER:
NDA 20-441/S001

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APPLICATION NUMBER:
NDA 20-441/S001

APPROVAL LETTER

NDA 20-441/S-001

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

Attention: Dennis Bucceri
Vice President
Regulatory Affairs

Dear Mr. Bucceri:

Please refer to your supplemental new drug application dated August 14, 1997, received August 15, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pulmicort Turbuhaler (budesonide inhalation powder) 200 mcg and 400 mcg.

The supplemental application provides for allowing [redacted] to be an alternate supplier of 16α-hydroxyprednisolone and budesonide.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely yours,

Guirag Poochikian, Ph.D.
Chemistry Team Leader, DNDC II
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-441
HFD-570/Div. Files
HFD-570/CSO/G.Trout
HFD-570/Ng
HFD-570/Koble
HFD-570/Poochikian
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: GST/February 13, 1998/n:\staff\troutg\20441.let

Initialed by: Schumaker/2-13-98
Ng/2-13-98

Final: LGrimshaw/2-13-98

APPROVAL (AP)