CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-441/S002

ADMINISTRATIVE DOCUMENTS

EXCLUSIVITY SUMMARY for NDA # 20441/S-002

Trade Name: Pulmicort Turbuhaler
Generic Name: budesonide powder for oral inhalation
Applicant Name Astra Pharmaceuticals, L.P. **HFD-570**

Approval Date: **October 8, 1998**

PART I IS AN EXCLUSIVITY DETERMINATION NEEDED?

1. An exclusivity determination will be made for all original applications, but only for certain supplements. Complete Parts II and III of this Exclusivity Summary only if you answer "yes" to one or more of the following questions about the submission.

   a) Is it an original NDA?

   YES /___/ NO /_X_/

   b) Is it an effectiveness supplement?

   YES /_X_/ NO /___/

   If yes, what type? (SE1, SE2, etc.) SE2

   c) Did it require the review of clinical data other than to support a safety claim or change in labeling related to safety? (If it required review only of bioavailability or bioequivalence data, answer "no.")

   YES /_X_/ NO /___/

   If your answer is "no" because you believe the study is a bioavailability study and, therefore, not eligible for exclusivity, EXPLAIN why it is a bioavailability study, including your reasons for disagreeing with any arguments made by the applicant that the study was not simply a bioavailability study.

   If it is a supplement requiring the review of clinical data but it is not an effectiveness supplement, describe the change or claim that is supported by the clinical data:

PART II FIVE-YEAR EXCLUSIVITY FOR NEW CHEMICAL ENTITIES
(Answer either #1 or #2, as appropriate)

1. Single active ingredient product.

Has FDA previously approved under section 505 of the Act any drug product containing the same active moiety as the drug under consideration? Answer "yes" if the active moiety (including other esterified forms, salts, complexes, chelates or clathrates) has been previously approved, but this particular form of the active moiety, e.g., this particular ester or salt (including salts with hydrogen or coordination bonding) or other non-covalent derivative (such as a complex, chelate, or clathrate) has not been approved. Answer "no" if the compound requires metabolic conversion (other than deesterification of an esterified form of the drug) to produce an already approved active moiety.

YES /_X_/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA # 20-233 Rhinocort Nasal Spray NDA# 20-441 Pulmicort Turbuhaler

NDA #_____ NDA #_____

2. Combination product.

If the product contains more than one active moiety (as defined in Part II, #1), has FDA previously approved an application under section 505 containing any one of the active moieties in the drug product? If, for example, the combination contains one never-before-approved active moiety and one previously approved active moiety, answer "yes." (An active moiety that is marketed under an OTC monograph, but that was never approved under an NDA, is considered not previously approved.)

YES /___/ NO /___/

If "yes," identify the approved drug product(s) containing the active moiety, and, if known, the NDA #(s).

NDA #

NDA #

(b) Did the applicant submit a list of published studies relevant to the safety and effectiveness of this drug product and a statement that the publicly available data would not independently support approval of the application?

YES /___/ NO /_X_/

(1) If the answer to 2(b) is "yes," do you personally know of any reason to disagree with the applicant's conclusion? If not applicable, answer NO.

YES /___/ NO /_X_/

If yes, explain:_____

(2) If the answer to 2(b) is "no," are you aware of published studies not conducted or sponsored by the applicant or other publicly available data that could independently demonstrate the safety and effectiveness of this drug product?

YES /___/ NO /_X_/

If yes, explain:_____

(c) If the answers to (b)(1) and (b)(2) were both "no," identify the clinical investigations submitted in the application that are essential to the approval:

Investigation #1, Study # DS-004-0009

Investigation #2, Study #

Investigation #3, Study #

3. In addition to being essential, investigations must be "new" to support exclusivity. The agency interprets "new clinical investigation" to mean an investigation that 1) has not been relied on by the agency to demonstrate the effectiveness of a previously approved drug for any indication and 2) does not duplicate the results of another investigation that was relied on by the agency to demonstrate the effectiveness of a previously approved drug product, i.e., does not redemonstrate something the agency considers to have been demonstrated in an already approved application.

c) If the answers to 3(a) and 3(b) are no, identify each "new" investigation in the application or supplement that is essential to the approval (i.e., the investigations listed in #2(c), less any that are not "new"):

Investigation #1, Study # DS-004-0009

Investigation #2, Study #

Investigation #3, Study #

4. To be eligible for exclusivity, a new investigation that is essential to approval must also have been conducted or sponsored by the applicant. An investigation was "conducted or sponsored by" the applicant if, before or during the conduct of the investigation, 1) the applicant was the sponsor of the IND named in the form FDA 1571 filed with the Agency, or 2) the applicant (or its predecessor in interest) provided substantial support for the study. Ordinarily, substantial support will mean providing 50 percent or more of the cost of the study.

a) For each investigation identified in response to question 3(c): if the investigation was carried out under an IND, was the applicant identified on the FDA 1571 as the sponsor?

Investigation #1
IND #_____ YES /_X_/ ! NO /___/ Explain: _____

Investigation #2
IND #_____ YES /___/ ! NO /___/ Explain: _____

Investigation #3
IND #_____ YES /___/ ! NO /___/ Explain: _____

(b) For each investigation not carried out under an IND or for which the applicant was not identified as the sponsor, did the applicant certify that it or the applicant's predecessor in interest provided substantial support for the study?

Investigation #1

YES /___/ Explain _____ ! NO /___/ Explain _____

_____ ! _____

_____ ! _____

PEDIATRIC PAGE

(Complete for all original application and all efficacy supplements)

NDA/BLA Number:	20441	**Trade Name:**	PULMICORT/TURBUHALER (BUDESONIDE)
Supplement Number:	2	**Generic Name:**	BUDESONIDE
Supplement Type:	SE2	**Dosage Form:**	Aerosol, Metered; Inhalation
Regulatory Action:	AP	**Proposed Indication:**	Once daily dosing

IS THERE PEDIATRIC CONTENT IN THIS SUBMISSION? YES

What are the INTENDED Pediatric Age Groups for this submission?

____NeoNates (0-30 Days)
____Infants (1-24 Months)
__X__Other Age Groups (listed): 6-12 years of age
____Children (25 Months-12 years)
__X__Adolescents (13-18 Years)

Label Status	ADEQUATE Labeling for ALL PEDIATRIC ages
Formulation Status	NO NEW FORMULATION is needed
Studies Needed	STUDIES needed. Applicant in NEGOTIATIONS with FDA
Study Status	Protocols are under discussion. Comment attached

Are there any Pediatric Phase 4 Commitments in the Action Letter for the Original Submission? YES

COMMENTS:
This supplement was approved for maintenance but NOT for initiation of therapy. Only children 6 years and above with mild to moderate asthma who are well controlled on inhaled corticosteroids are approved for once daily dosing. FDA has strongly recommended that the applicant study the systemic effects of once daily administration in the morning versus the evening in pediatric patients, but this is NOT a Phase 4 commitment. D. Hilfiker, 10-08-98

This Page was completed based on information from a PROJECT MANAGER/CONSUMER SAFETY OFFICER, DAVID HILFIKER

Signature /S/ Date 10-8-98

cc: Original NDA 20-441/S-002
HFD-570/ Division File
HFD-570/ Hilfiker
HFD-570/ Schumaker

APPEARS THIS WAY
ON ORIGINAL

Debarment Certification

This certifies that Astra USA, Inc. has not used in any capacity any person identified by the United States Food and Drug Administration on the recent Debarment List.

Further, we certify that Astra USA, Inc. will not use the services in any capacity of anyone debarred by the United States Food and Drug Administration.

The following is a list of all relevant convictions (for which a person can be debarred) as described in section 306 (a) and (b). The list covers the past five (5) years for persons employed and/or affiliated with Astra USA, Inc. (including contractors) and responsible for the development of data and information to support approval of NDA 20-441 for Pulmicort Turbuhaler® (budesonide inhalation powder).

Person	Date of Conviction	Charge
None	None	None

10/6/97

Dennis J. Bugeri
Vice President
Regulatory Affairs

Date

APPEARS THIS WAY
ON ORIGINAL