CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
21-929

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review

14 Feb 2006

NDA: 21-929
     21-929 BC

Drug Product Name
Proprietary: Symbicort® MDI
Non-proprietary: Budesonide/formoterol
inhalation aerosol

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

<table>
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<tr>
<th>Letter</th>
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<th>Consult Sent</th>
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<td>21-OCT-2005</td>
<td>24-OCT-2005</td>
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Submission History (for amendments only) – N/A

Applicant/Sponsor
Name: AstraZeneca LP
Address: 1800 Concord Pike
         P.O. Box 8355
         Wilmington, DE 19803-8355

Representative: Mark A. Desiato
Director, Regulatory Affairs

Telephone: (302) 885-1386

Name of Reviewer: Anastasia G. Lolas

Conclusion: Recommended for approval based on product quality microbiology
Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommended for approval based on product quality microbiology

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The microbial limit specifications and testing procedures are reviewed for this new inhalation drug product and its two active drug substances.

B. Brief Description of Microbiology Deficiencies – None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature ____________________________
   Anastasia G. Lolas

B. Endorsement Block
   Stephen E. Langille, Ph.D.

C. CC Block
   N/A
6 Page(s) Withheld

6 Trade Secret / Confidential

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Anastasia Lolus
2/14/2006 10:43:11 AM
MICROBIOLOGIST

Stephen Langille
2/14/2006 10:49:35 AM
MICROBIOLOGIST