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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

Letter	Stamp	Consult Sent	Assigned to Reviewer
23-SEP-2005	23-SEP-2005	13-JAN-2006	17-JAN-2006
21-OCT-2005	24-OCT-2005	N/A	N/A

**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

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**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

         Draft Labeling

         Deliberative Process

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/s/

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

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