# CLINICAL PHARMACOLOGY REVIEW

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| NDA: | 20-983 (b) (4) | Submission Date(s): | Sept 28, 2007 |
| Brand Name | | Ventolin HFA | |
| Generic Name | | Albuterol sulfate HFA inhalation aerosol | |
| Reviewer | | Wei Qiu, Ph.D. | |
| Secondary Review | | Chandrahas Sahajwalla, Ph.D. | |
| OCP Division | | DCPII | |
| OND division | | DPAP | |
| Sponsor | | GSK | |
| Submission Type | | (b) (4) | |
| Formulation; Strength(s) | | Inhalation aerosol; 108 mcg albuterol sulfate or 90 mcg of albuterol base per actuation | |
| Indication | | Treatment or prevention of bronchospasm in adults and children 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older. | |

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## 1   Executive Summary

Ventolin HFA® (albuterol sulfate HFA inhalation aerosol) is a β2-adrenergic receptor agonist and is currently indicated for the treatment or prevention of bronchospasm with reversible obstructive airway disease and prevention of exercise-induced bronchospasm in patients 4 years of age and older.

Ventolin HFA® is supplied as a suspension of micronized albuterol sulfate in hydrofluoroalkane-(HFA)134a propellant in an aluminum canister fitted with an actuator. Each actuation delivers 108mcg of albuterol sulfate or 90mcg of albuterol base from the actuator.

(b) (4)

No Clinical Pharmacology and biopharmaceutics studies were conducted as part of this submission.

Proposed labeling changes (see Appendix 2.1 Sponsor's Proposed Labeling) under section DRUG INTERACTIONS (7.3) and (7.4) are acceptable. Therefore, there are no comments for sponsor at this time.

# <u>16</u> Page(s) Withheld

_____ Trade Secret / Confidential

__**X**__ Draft Labeling

_____ Deliberative Process

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3/7/2008 04:44:14 PM
BIOPHARMACEUTICS



Chandra Sahajwalla
3/11/2008 12:22:05 PM
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