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.

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.
16 Page(s) Withheld

_____ Trade Secret / Confidential

X Draft Labeling

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

/s/

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

Chandra Sahajwalla
BIOPHARMACEUTICS