

CLINICAL PHARMACOLOGY REVIEW

NDA	205920
Submission Date	6/28/2016
Brand Name	Primatene [®]
Generic Name	(b) (4) 125 mcg/inhalation (Epinephrine Inhalation Aerosol USP)
Clinical Pharmacology Reviewer	Jianmeng Chen, M.D., Ph.D.
Clinical Pharmacology Team Leader	Bhawana Saluja, Ph.D.
OCP Division	Clinical Pharmacology II
OND Division	Nonprescription Drug Products, and Pulmonary, Allergy, and Rheumatology Products
Sponsor/Authorized Applicant	Armstrong Pharmaceuticals INC
Submission Type; Code	NDA resubmission
Formulation; Strength(s)	125 mcg/inhalation
Indication	Temporary relief of mild symptoms of intermittent asthma (as an OTC product) in adults and children 12 years of age and older.
Dosage Regimen	1 to 2 inhalations for each dose. Start with 1 inhalation, wait at least 1 minute. If not relieved, use once more. Wait at least 4 hours between doses. Do not use more than 8 inhalations in 24 hours. Children under 12 years of age: Do not use.

This is an amendment for the clinical pharmacology review (DARRTS date 12/9/2016) for NDA 205920.

While we considered that the assessment of PK profile may not be feasible for this product at the proposed therapeutic dose in patients 4-11 years old, the medical officers Dr. Sofia Chaudhry (DPARP) and Dr. Ryan Raffaelli (DNDP) suggested that some pediatric PK be collected at the therapeutic dose for this age group, to make sure that the systemic epinephrine exposure post-dose in patients 4-11 years old is not unexpectedly higher as compared to other populations. Below is our revised recommendation for PK assessment in 4-11 years old:

Assess epinephrine exposure around T_{max} at the proposed test dose strengths in the

safety and efficacy trial.

(b) (4)

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/s/

JIANMENG CHEN
12/22/2016

BHAWANA SALUJA
12/23/2016