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APPLICATION NUMBER:

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PHARMACOLOGY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PHARMACOLOGY/TOXICOLOGY NDA/BLA REVIEW AND EVALUATION

Application number: NDA 205-029
Supporting document/s: 0000
Applicant's letter date: December 4, 2012
CDER stamp date: December 4, 2012
Product: Epinephrine (HCL) Injection
USP, 1:1000 (1mg/mL)
Indication: Treatment of increasing systemic arterial blood pressure in acute hypotensive states associated with septic shock
Applicant: Belcher Pharmaceuticals, LLC (Belcher)
Review Division: Cardiovascular and Renal Products
Reviewer: Rama Dwivedi, Ph.D.
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