CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209260Orig1s000

STATISTICAL REVIEW(S)

NDA 209260

Applicant: Fresenius Kabi
Drug: Atropine Sulfate Injection (0.4 mg/ml)
Indication: Temporary blockade of severe or life threatening muscarinic effects

The sponsor submitted this NDA via 505(b)(2) pathway to seek approval for Atropine Sulfate Injection, USP, 0.4 mg/mL in a 20 mL multi-dose glass vial for intramuscular (IM), intravenous (IV) or subcutaneous (SC) use. The Reference Listed Drug (RLD) is Atropine Sulfate (0.1 mg/mL) injection in Ansyr Plastic Syringe. The RLD is manufactured by Hospira, Inc.

The submission is literature based and contains no clinical data. No statistical review is performed.

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/s/

JIALU ZHANG
12/07/2017

HSIEN MING J HUNG
12/08/2017