## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 201444Orig1s000

## **STATISTICAL REVIEW(S)**

REV-BIOMETRICS-02 (Review Noted (NAI)) NDA-201444 ORIG-1 Supporting Document 1 NEW/NDA Submit Date: 05/21/2010 - FDA Received Date: 05/21/2010

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No clinical data in this submission. Medical Officer says the reference articles do not need statistical review. No stats review needed for this NDA.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-201444	ORIG-1	HOPE PHARMACEUTICA LS	SODIUM NITRITE INJECTION

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KATHERINE B MEAKER 06/16/2010

DIONNE L PRICE 06/17/2010 I concur that a stats review is not needed.