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RESEARCH**

APPLICATION NUMBER:

209463Orig1s000

STATISTICAL REVIEW(S)

REV-BIOMETRICS-02 (Review Noted (NAI))

NDA-209463

ORIG-1

Supporting Document 1

User Fee/Coversheet

New/NDA

Form 3674

Submit Date: 06/02/2016 - FDA Received Date: 06/02/2016

The application was under Section 505(b)(2). The reference listing drug was pantoprazole sodium which was approved on March 22, 2001 under NDA N020988. There was no efficacy or safety data submitted for this application. Therefore no action is indicated for statistical review on NDA 209463.

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/s/

LING LAN
07/22/2016

YEH FONG CHEN
07/25/2016