

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

200656Orig1s000

STATISTICAL REVIEW(S)

NDA 200656 is a 505(b)(2) application with no new clinical studies which support efficacy claims. Hence this NDA review is designated as No Action Indicated (NAI) by the statistical review team.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BEHRANG D VALI
03/23/2011

MICHAEL E WELCH
03/24/2011