APPLICATION NUMBER:

206995Orig1s000

PROPRIETARY NAME REVIEW(S)
Date of This Review: December 3, 2014
Application Type and Number: NDA 206995
Product Name and Strength: Iressa (Gefitinib) Tablets, 250 mg
Product Type: Single Ingredient
Rx or OTC: Rx
Applicant/Sponsor Name: AstraZeneca
Submission Date: October 3, 2014
Panorama #: 2014-38519
DMEPA Primary Reviewer: Davis Mathew, PharmD
DMEPA Associate Director: Chi-Ming (Alice) Tu, PharmD
1 INTRODUCTION

The proposed proprietary name, Iressa, was found acceptable in OSE Review # 2014-17173, dated July 21, 2014 under IND 120992. We note that product characteristics are the same for NDA 206995 currently under review as the IND. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Iressa, is acceptable from both a promotional and safety perspective under the NDA 206995.

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

1.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Iressa, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your October 3, 2014 submission are altered, the name must be resubmitted for review.
REFERENCES

1. Mathew D, Proprietary Name Review for Iressa (IND 120992). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014-07-21. OSE RCM No.: 2014-17173
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/s/

DAVIS MATHEW  
12/03/2014

CHI-MING TU  
12/04/2014

Reference ID: 3667493