

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206995Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**PROPRIETARY NAME REVIEW MEMORANDUM**

Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

**\*\*\* This document contains proprietary information that cannot be released to the public\*\*\***

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

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## **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/  
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DAVIS MATHEW  
12/03/2014

CHI-MING TU  
12/04/2014