CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205434Orig1s000

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

Proprietary Name Memorandum

Date:	November 13, 2013
Reviewer:	Chi-Ming (Alice) Tu, PharmD Division of Medication Error Prevention and Analysis
Team Leader:	Jo Wyeth, PharmD Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Flonase Allergy Relief (Fluticasone Propionate) Spray, 50 mcg per spray
Application Type/Number:	NDA 205434
Document Number:	3
Applicant/Sponsor:	GlaxoSmithKline Consumer Healthcare
OSE RCM #:	2013-2585

*** This document contains proprietary and confidential information that should not be released to the public.***

1 INTRODUCTION

The proposed proprietary name, Flonase Allergy Relief, was found acceptable in OSE Review# 2013-1423, dated September 18, 2013 under IND 109805. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Flonase Allergy Relief, is acceptable from both a promotional and safety perspective under the NDA 205434.

If you have further questions or need clarifications, please contact Sue Kang, OSE project manager, at 301-796-4216.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 7, 2013 submission are altered, the name must be resubmitted for review.

2 REFERENCES

1. OSE Review# 2013-1423: Proprietary Name Review for Flonase Allergy Relief (Fluticasone Propionate), September 18, 2013.

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/s/

CHI-MING TU
11/13/2013

JO H WYETH
11/13/2013