

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
205747Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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)

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Date of This Review:	February 12, 2015
Application Type and Number:	NDA 205747
Product Name and Strength:	Humalog KwikPen (insulin lispro) for injection, 200 units/mL
Product Type:	Combination Product (Drug + Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Eli Lilly
Panorama #:	2014-45414
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

1 INTRODUCTION

Eli Lilly submitted a complete response to FDA complete response letter on November 26, 2014. The proposed proprietary name, Humalog KwikPen, was found acceptable in OSE Review# 2013-2473, dated January 7, 2014.¹ In their request for review of proprietary name, Eli Lilly states that drug product characteristics have not changed since the October 28, 2013 submission.

This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Humalog KwikPen, is acceptable from both a promotional and safety perspective.

1.1 COMPARISON OF MARKETED AND PROPOSED HUMALOG KWIKPEN PRODUCTS

There are three Humalog Kwikpens currently marketed in the United States. The proposed product differs from those marketed in regards to concentration per mL and total amount of insulin per Kwikpen (see Table 1).

<i>Proprietary Name</i>	Humalog Kwikpen (proposed name)	Humalog Kwikpen	Humalog Mix 50/50 Kwikpen	Humalog Mix 75/25 Kwikpen
<i>Established Name</i>	Insulin Lispro (Human)	Insulin Lispro (Human)	Insulin Lispro Protamine and Insulin Lispro (Human)	Insulin Lispro Protamine and Insulin Lispro (Human)
<i>Marketing Status</i>	Proposed	Marketed		
<i>Concentration (units per mL)</i>	200 units/mL	100 units/mL		
<i>How Supplied (total units per Kwikpen)</i>	600 units/3 mL	300 units/3 mL		
<i>Units/Click</i>	1 click=1 unit (total of 60 units can be dispensed from any pen)			

1.2 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products via e-mail on January 27, 2015. At that time we also requested additional

¹ Vee, S. Proprietary Name Review for Humalog KwikPen (NDA 205747). 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 Jan 7. 34 p. OSE RCM No.: 2013-2473.

information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products on January 27, 2015, they stated no additional concerns with the proposed proprietary name, Humalog Kwikpen.

2 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

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/s/

SARAH K VEE
02/12/2015

YELENA L MASLOV
02/12/2015

**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 Review Memo

Date: January 7, 2014

Reviewer: Sarah K. Vee, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Humalog Kwikpen
(Insulin Lispro) Injection, 200 units/mL

Application Type/Number: NDA 205747

Applicant/Sponsor: Eli Lilly and Company

OSE RCM #: 2013-2473

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1 INTRODUCTION

This memo evaluates the proposed proprietary name, Humalog KwikPen, from a safety and promotional perspective.

1.1 COMPARISON OF MARKETED AND PROPOSED HUMALOG KWIKPEN PRODUCTS

There are three Humalog Kwikpens currently marketed in the United States. The proposed product differs from those marketed in regards to concentration per mL and total amount of insulin per Kwikpen (see Table 1).

<i>Proprietary Name</i>	Humalog Kwikpen (proposed name)	Humalog Kwikpen	Humalog Mix 50/50 Kwikpen	Humalog Mix 75/25 Kwikpen
<i>Established Name</i>	Insulin Lispro (Human)	Insulin Lispro (Human)	Insulin Lispro Protamine and Insulin Lispro (Human)	Insulin Lispro Protamine and Insulin Lispro (Human)
<i>Marketing Status</i>	Proposed	Marketed		
<i>Concentration (units per mL)</i>	200 units/mL	100 units/mL		
<i>How Supplied (total units per Kwikpen)</i>	600 units/3 mL	300 units/3 mL		
<i>Units/Click</i>	1 click=1 unit (total of 60 units can be dispensed from any pen)			

1.2 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on December 23, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on January 6, 2014, they stated no additional concerns with the proposed proprietary name, Humalog Kwikpen.

1.3 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and DMEP concurred with the findings of OPDP's promotional assessment of the proposed name.

2 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Margarita Tossa, OSE project manager, at 301-796-4053.

2.1 COMMENTS TO THE APPLICANT

In the proprietary name review request unacceptable letter for Humalog (b) (4)
Kwikpen, dated August 8, 2013 (b) (4)

Our thinking regarding your proposed product, insulin lispro 200 units/mL, has not changed. Thus, we find the proposed proprietary name, Humalog KwikPen, acceptable for this product.

If any of the proposed product characteristics as stated in your October 28, 2013 submission are altered, the name must be resubmitted for review.

REFERENCES

OSE Review #2013-1189 Humalog (b) (4) Kwikpen, Dated August 8, 2013, Reasol S. Agustin, PharmD.

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/s/

SARAH K VEE
01/07/2014

YELENA L MASLOV
01/07/2014

**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 Review

Date: August 8, 2013

Reviewer: Reasol S. Agustin, PharmD
Division of Medication Error Prevention and Analysis

Team Leader: Yelena Maslov, PharmD
Division of Medication Error Prevention and Analysis

Division Director: Carol Holquist, RPh
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Humalog ^{(b) (4)} Kwikpen
(Insulin Lispro) Injection, 200 units/mL

Application Type/Number: NDA 205747

Applicant/Sponsor: Eli Lilly and Company

OSE RCM #: 2013-1189

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/s/

REASOL AGUSTIN
08/08/2013

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