CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208751Orig1s000

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)

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

Date of This Review:	May 23, 2017
Application Type and Number:	NDA 208751
Product Name and Strength:	Fiasp (insulin aspart injection) 100 units/mL Fiasp FlexTouch (insulin aspart) 100 units/mL
Total Product Strength:	1000 units per 10 mL vial 300 units per 3 mL prefilled pen
Product Type:	Single Ingredient, Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novo Nordisk Inc.
Panorama #:	2017-14050537 and 2017-14162760
DMEPA Primary Reviewer:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Team Leader:	Hina Mehta, PharmD
Associate Director (Acting)	Mishale Mistry, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary names, Fiasp and Fiasp FlexTouch, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4) for this product, which was reviewed in OSE Review #2013-16671.[a]

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Fiasp, for review under IND 106878 and the Division of Medication Error Prevention and Analysis (DMEPA) found the name acceptable in OSE Review #2013-16671, dated May 7, 2014.[a] The Applicant resubmitted the name Fiasp for review under NDA 208751 on December 9, 2015; however, the Division of Metabolism and Endocrinology (DMEP) had concerns with the proprietary name Fiasp for the proposed product and held a teleconference with the Applicant on February 10, 2016.[b] Specifically, the DMEP had not made a determination regarding the Applicant's statement on the faster onset of this insulin aspart product and they were unable to determine if there are any clinical benefits compared to the marketed insulin aspart at that stage of the review cycle. Therefore, the DMEP determined that the propose name could be misleading. Following the teleconference, the Applicant withdrew the name, Fiasp, for consideration on February 11, 2016[c] and submitted the names (b) (4)*** and (b) (4) FlexTouch*** for review on February 29, 2016. However, (b) (4)*** was found unacceptable in OSE Review #2016-2924779.[d] Thus, the Applicant submitted the names (b) (4)*** and (b) (4) FlexTouch*** for review on June 10, 2016 and these names were found to be acceptable in OSE Review # 2016-8522346 on July 26, 2016.[e] However, on December 15, 2016, DMEPA amended the decision regarding the acceptability of the names (b) (4)*** and (b) (4) FlexTouch*** because DMEPA determine that the name (b) (4)*** is vulnerable to name confusion with another proposed proprietary name that was under review.[f]

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[a] Vee S. Proprietary Name Review for Fiasp (IND 106878). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Feb 22. 20p. OSE RCM No. 2013-16671.

[b] Thomas T. Memorandum of Meeting Minutes for Fiasp (insulin aspart NDA 208751) on 2016 Feb 10. Silver Spring (MD): FDA, CDER, OND, DMEP (US); 2016 Feb 22.

[c] Novo Nordisk Inc. NDA Amendment-Proprietary Name Withdrawal (NDA 208751 faster acting insulin aspart). Plainsboro (NJ): Novo Nordisk Inc. 2016 Feb 11.

[d] Vee S. Proprietary Name Review for (b) (4) (NDA 208751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Apr 21. 29p. OSE RCM No. 2016-2924779.

[e] Vee S. Proprietary Name Review for (b) (4) (NDA 208751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 July 26. 24p. OSE RCM No. 2016-8522346.

[f] Conrad A. Proprietary Name Memorandum for (b) (4) (NDA 208751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Dec 15. 4 p. OSE RCM No. 2016-8522346-1.

Thus, the Applicant resubmitted the names Fiasp and Fiasp FlexTouch for review on January 12, 2017. Per email correspondence with DMEP dated January 9, 2017, DMEP no longer has concerns regarding the name Fiasp.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 29, 2017 proprietary name submission.

- Intended Pronunciation: fee' asp
- Active Ingredient: insulin aspart
- Indication of Use: insulin analog indicated to improve glycemic control in adults with diabetes mellitus
- Route of Administration: subcutaneous and intravenous injection
- Dosage Form: injection
- Strength: 100 units/mL
- Dose and Frequency: (b) (4) . Fiasp® should be given at the start of a meal or post-meal (within 20 minutes after starting a meal).
- How Supplied: 3 mL prefilled disposable pen injector or 10 mL vials
- Storage: Unused--store in a refrigerator between 2° and 8°C (36° to 46°F). In use--keep at temperatures below 30°C (86°F) or in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 28 days.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product via their April 13, 2017 email. DMEPA and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name.[g]

[g] USAN stem search conducted on April 26, 2017.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed names, Fiasp and Fiasp FlexTouch, are comprised of the root name Fiasp and the modifier FlexTouch. The Applicant did not provide an intended meaning for the proposed name Fiasp in the submission. However, the Applicant noted in their previous submission that the name FIAasp was derived from Faster Acting Insulin Aspart.[h]

The appropriateness of the modifier, FlexTouch, was previously evaluated in OSE Review # 2016-8522346.[i]

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE April 14, 2017 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of this review.

2.2.4 FDA Name Simulation Studies

Seventy-seven (77) practitioners participated in DMEPA's prescription studies for Fiasp and 70 practitioners participated in the prescription studies for Fiasp FlexTouch. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[j] identified 18 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the 20 names retrieved from our POCA search and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair:	17

[h] Novo Nordisk Inc. Response to FDA Advice and Information Request for Faster-acting insulin aspart (IND 106878). Plainsboro (NJ): Novo Nordisk Inc; 2013 Feb 8.

[i] Vee S. Proprietary Name Review for (b) (4) (NDA 208751). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 July 26. 24p. OSE RCM No. 2016-8522346.

[j] POCA search conducted on April 17, 2017 in version 4.0.

combined match percentage score ≥55% to ≤ 69%	
Low similarity name pair: combined match percentage score ≤54%	2

2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 20 names contained in Table 1 determined that these 20 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 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 May 17, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMEP on May 23, 2017, they stated no additional concerns with the proposed proprietary names Fiasp and Fiasp FlexTouch.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

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

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Fiasp and Fiasp FlexTouch, and have concluded that these names are acceptable.

If any of the proposed product characteristics, as stated in your January 12, 2017 and March 29, 2017 submissions, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [k]

[k] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[1]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

[1] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

   When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.

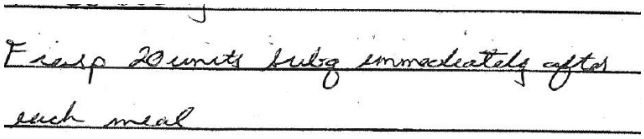
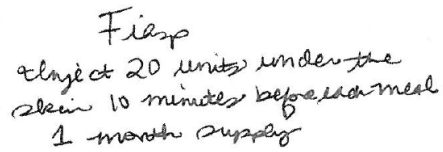
<table>
<tr><td></td><td colspan="2">• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?
• Is there different number or placement of cross-stroke or dotted letters present in the names?
• Do the infixes of the name appear dissimilar when scripted?
• Do the suffixes of the names appear dissimilar when scripted?</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Fiasp Study (Conducted on April 17, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Fiasp inject 20 units under the skin 10 minutes before each meal # 1 month supply
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Fiasp
As of Date 5/8/2017

299 People Received Study
77 People Responded

Study Name: Fiasp

Total **23** **22** **32**

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
FEAS	0	1	0	1
FEASP	0	3	0	3
FEASPT	0	1	0	1
FEEASP	0	1	0	1
FIAP	1	0	0	1
FIARP	1	0	1	2
FIAS	0	1	0	1
FIASC	0	1	0	1
FIASP	16	12	12	40
FIAST	0	1	0	1
FIERP	0	0	1	1
FIESP	3	0	4	7
FIEUP	0	0	1	1
FILSP	2	0	0	2
FIUSP	0	0	1	1
FREISP	0	0	2	2
FRESP	0	0	3	3
FRIAP	0	0	1	1
FRIASP	0	0	1	1
FRIESP	0	0	3	3
FRRESP	0	0	1	1
FRUSP	0	0	1	1
VIASP	0	1	0	1

Figure 2. Fiasp FlexTouch Study (Conducted on April 20, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Fiasp FlexTouch 20 units sub Q Immediately after each meal **Outpatient Prescription:** Fiasp FlexTouch inject 20 units under the skin 10 minutes before each meal #1 month supply	Fiasp FlexTouch inject 20 units under the skin 10 minutes before each meal #1 month supply

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Fiasp FlexTouch
As of Date 5/8/2017

298 People Received Study
70 People Responded

Study Name: Fiasp FlexTouch

Total **31** **17** **22**

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CEASPE FLEXTOUCH	0	1	0	1
CEASSSEPTOUCH	0	1	0	1
CEAST FLEXTOUCH	0	1	0	1
CIASP	0	1	0	1
CIASP FLEXTOUCH	0	1	0	1
CIAST FLEXTOUCH	0	1	0	1
FEAST FLEX TOUCH	0	1	0	1
FEASTE	0	1	0	1
FIAP FLEXTOUCH	1	0	0	1
FIARP FLEXTOUCH	2	0	0	2
FIASP FL;EX TOUCH	0	0	1	1
FIASP FLEX TOUCH	9	1	19	29
FIASP FLEXTOUCH	14	1	2	17
FIAST FLEXTOUCH	0	1	0	1
FIASYS FLEXTOUCH	1	0	0	1
FIAZO FLEXITOUCH	1	0	0	1
FIAZP	1	0	0	1
FIAZS FLEXTOUCH	1	0	0	1
FIERUP FLEXTOUCH	1	0	0	1
SEASP FLEXTOUCH	0	1	0	1
SEASP SLIMTOUCH	0	1	0	1
SEAST FLEXTOUCH	0	2	0	2
SEEAST FLEXTOUCH	0	1	0	1
SIASP FLEXTOUCH	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	Proposed name: Fiasp Established name: insulin aspart Dosage form: solution Strength(s): 100 units/mL Usual Dose: individualized dose administered at the start of the meal or post meal	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Fiasp***	100	This name is the subject of the review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Fiv-Asa	60
2.	Frais	59
3.	Fasprin	58
4.	Fastin	58
5.	Niaspan	57
6.	Riastap	56
7.	A-Spas	52

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Fiasp Established name: insulin aspart Dosage form: solution Strength(s): 100 units/mL Usual Dose: individualized dose administered at the start of the meal or post meal	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names

No.	Proposed name: Fiasp Established name: insulin aspart Dosage form: solution Strength(s): 100 units/mL Usual Dose: individualized dose administered at the start of the meal or post meal	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Fanapt	59	The letter in the 2nd position (i vs. a) of the name pair and the last letter (t) in Fanapt provide some orthographic differences. The first and second syllables of this name pair sound different. We note that there is an overlap in strength between the 10 mg dose of Fanapt and the 100 units/mL concentration of Fiasp. However, we expect that the risk for confusion to be low because the desired formulation and route of administration for each product would be specified during prescribing and the desired number of units of Fiasp would be indicated versus the 100 units/mL concentration.
2.	Fiorpap	59	The lengths of the names differ by two letters. The infix and suffix (-or- and -pap) of this name appear dissimilar from Fiasp when scripted. The second and last syllables of this name sound different from Fiasp.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Aranesp	44
2.	Ziac	44

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	4 Face Up	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
2.	5 Face Up	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Face Up	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Face Up #2	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Face Up #3	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[m].

No.	Name	POCA Score (%)
1.	Silapap	58
2.	Pacis	56
3.	Sani-Supp	56

[m] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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/s/

ARIANE O CONRAD
05/23/2017

HINA S MEHTA
05/24/2017

MISHALE P MISTRY
05/29/2017

PROPRIETARY NAME 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*****

Date of This Review:	December 15, 2016
Application Type and Number:	NDA 208751
Product Name and Strength:	(b) (4) (insulin aspart injection), 100 units/mL (b) (4) FlexTouch (insulin aspart injection), 100 units/mL
Total Product Strength:	1,000 units/10 mL vials 300 units/3 mL pen injector
Product Type:	Single ingredient and Combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novo Nordisk
Panorama #:	2016-8522346-1
DMEPA Primary Reviewer:	Ariane O. Conrad, PharmD, BCACP, CDE
DMEPA Director:	Todd D. Bridges, RPh.

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/s/

ARIANE O CONRAD
12/15/2016

TODD D BRIDGES
12/15/2016

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:	July 26, 2016
Application Type and Number:	NDA 208751
Product Name and Strength:	(b) (4) (insulin aspart injection), 100 units/mL (b) (4) FlexTouch (insulin aspart injection), 100 units/mL
Product Type:	Combination: FlexTouch (Drug + Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novo Nordisk
Panorama #:	2016-8522346
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader (Acting):	Hina Mehta, PharmD
DMEPA Deputy Director:	Lubna Merchant, PharmD, MS

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SARAH K VEE
07/26/2016

HINA S MEHTA
07/26/2016

LUBNA A MERCHANT
07/26/2016

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:	April 21, 2016
Application Type and Number:	NDA 208751
Product Name and Strength:	(b) (4) (insulin aspart injection), 100 units/mL (b) (4) FlexTouch (insulin aspart injection), 100 units/mL
Product Type:	Combination: FlexTouch (Drug + Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	Novo Nordisk
Panorama #:	2016-2924779
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD
DMEPA Associate Director:	Lubna Merchant, PharmD, MS
DMEPA Director:	Todd Bridges, RPh

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/s/

SARAH K VEE
04/21/2016

YELENA L MASLOV
04/22/2016

LUBNA A MERCHANT
04/22/2016

TODD D BRIDGES
04/22/2016