CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213224Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	January 27, 2019
Application Type and Number:	NDA 213224
Product Name and Strength:	Bynfezia Pen (octreotide acetate), injection 2500 mcg/ml
Product Strength:	2,500 mcg/mL octreotide in a 2.8 mL single-patient-use pen.
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharmaceutical Industries (Sun Pharma)
Panorama #:	2019-34365344-1
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Bynfezia Pen, which was found conditionally acceptable under NDA 213224 on December 5, 2019.[a] Since our previous evaluation of this proposed proprietary name, we have learned that this product will be approved with a product strength of 2,500 mcg/mL octreotide in a 2.8 mL single-patient-use pen. (b) (4)

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names taking into account the change in product strength presentation. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Bynfezia Pen.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The January 24, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Bynfezia Pen.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Bynfezia Pen, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE, OSE project manager, at 301-796-2253.

[a] Fanari, M. Proprietary Name Review for Bynfezia Pen (NDA 213224). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Dec 5. Panorama No.: 2019-34365344.

4 REFERENCE

1. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELINA N FANARI
01/27/2020 12:07:54 AM

SEVAN H KOLEJIAN
01/27/2020 09:20:38 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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Date of This Review:	December 5, 2019
Application Type and Number:	NDA 213224
Product Name and Strength:	Bynfezia Pen (octreotide acetate), injection (b) (4) 2.8 ml (2.5 mg/mL)
Total Product Strength:	2.8 mL multi dose pen injector (calculated total strength: (b) (4)
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharmaceutical Industries (Sun Pharma)
Panorama #:	2019-34365344
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Bynfezia Pen, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Sun Pharma submitted their results from an internally conducted evaluation for this proposed proprietary name.

1.1 REGULATORY HISTORY

Sun Pharma previously submitted the proposed proprietary name, (b) (4)*** on April 5, 2019. However, we found the name, (b) (4)*** unacceptable due to potential confusion with another pending proposed proprietary name, Tepezza*** on June 18, 2019.[a]

Thus, Sun Pharma submitted the name, Bynfezia Pen, for review on September 11, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 11, 2019.

- Intended Pronunciation: ben-FEZ-ee-uh PEN
- Active Ingredient: octreotide acetate
- Indication of Use: For the treatment of acromegaly, severe diarrhea/flushing episodes associated with metastatic carcinoid tumors, and profuse watery diarrhea associated with vasoactive intestinal peptide (VIP) secreting tumors.
- Route of Administration: subcutaneous
- Dosage Form: injection (disposable multi-dose pen injector, for doses of 50 mcg, 100 mcg, 150 mcg and 200 mcg)
- Strength: 2.5 mg/mL in 2.8 mL pen injector (calculated total strength: (b) (4)
- Dose and Frequency: The initial dosage is usually 50 mcg administered (b) (4) three times daily. Upward dose titration is frequently required. Dosage information for patients with specific tumors follows.

  Acromegaly: (b) (4) initiated at 50 mcg three times daily. The (b) (4) (b) (4) 100 mcg three times a day, but some patients require up to 500 mcg three times a day (b) (4). Doses greater than 300 mcg/day seldom result in additional (b) (4) benefit, and if an increase in dose fails to provide additional benefit, (b) (4).

  Carcinoid Tumors: 100-600 mcg/(b) (4) in 2-4 divided doses for first 2 weeks

  VIP tumors: 200-300 mcg/(b) (4) in 2-4 divided doses for first 2 weeks

[a] Fanari, Melina. Proprietary Name Review for (b) (4) (NDA 213224). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jun 18. Panorama No. 2018-30640144.

- How Supplied: Package size of two 2.8 mL multi dose disposable pen injectors per carton
- Storage: In refrigerator 36°F to 46°F (2°C to 8° C) in the carton. Protect the pen from light. After first use store pens at controlled room temperature between 68°F to 77°F (20°C to 25°C). Excursions between 59°F (15°C) and 86°F (30°C) are allowed for up to 28 days.
- Reference Listed Drug/Reference Product: Sandostatin Injection; NDA 19667

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Bynfezia Pen would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Bynfezia Pen.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Bynfezia Pen.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Sun Pharma indicated in their submission that the proposed proprietary name, Bynfezia Pen, contains a modifier, 'Pen', which describes the type of device to deliver the drug product. This proprietary name is comprised of multiple words that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

The proposed name Bynfezia Pen is comprised of the root name, Bynfezia, and modifier, 'Pen'. The proposed modifier, 'Pen', refers to the autoinjector device. Although the term 'Pen' refers to a device type that is not unique to this product, the use of 'Pen' in the proposed name is consistent with currently marketed combination products with autoinjector device constituent parts that use the modifier "Pen'.

We acknowledge that omission and oversight of a modifier is cited in literature as a common cause of medication error.[c] If the modifier, 'Pen', is omitted, the correct product would likely be dispensed since Bynfezia is only available in the autoinjector device platform. We also note that 'Pen' is an abbreviation for Penicillin, Penicillamine, and Pentafraction, however we are

[b] USAN stem search conducted on September 12, 2019.

[c] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

unaware of any post marketing cases of 'Pen' being misinterpreted as penicillin, penicillamine, or pentafraction with currently marketed products that contain the 'Pen' modifier. Therefore, for the reasons described above, we find the use of the modifier, 'Pen', acceptable for this product.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 15, 2019 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) did not forward any comments or concerns relating to Bynfezia Pen at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-one practitioners participated in DMEPA's prescription studies for Bynfezia Pen. 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[d] identified 53 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 53 names retrieved from our POCA search and 17 names identified in the internal study conducted by Sun Pharmaceutical. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	52
Low similarity name pair: combined match percentage score ≤54%	18

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

Our analysis of the 70 names contained in Table 1 determined none of the names will pose a risk for confusion with Bynfezia Pen as described in Appendices C through H.

[d] POCA search conducted on November 27, 2019 in version 4.3.

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 November 25, 2019. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on November 27, 2019, they stated no additional concerns with the proposed proprietary name, Bynfezia Pen.

3 CONCLUSION

The proposed proprietary name, Bynfezia Pen, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO SUN PHARMACEUTICAL INDUSTRIES

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

If any of the proposed product characteristics as stated in your submission, received on September 11, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)

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.

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. [e]

[e] 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[f]. 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., 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

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

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 upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, 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. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 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 **with** overlapping or similar strengths or doses.

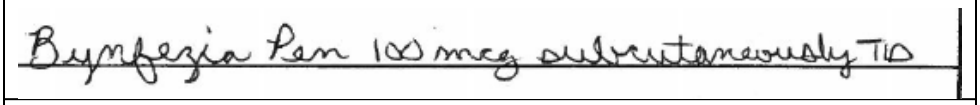
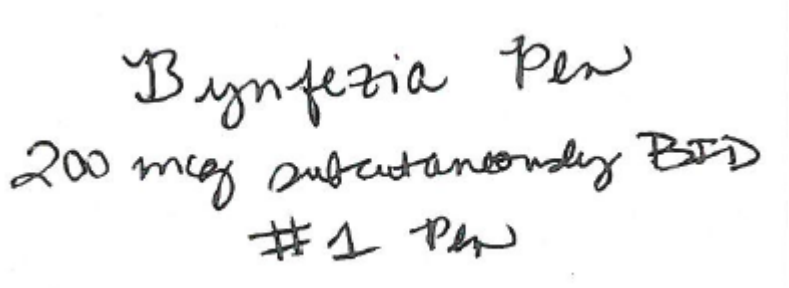
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?	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?

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. Bynfezia Pen Study (Conducted on September 30, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Bynfezia Pen Inject 200 mg subcutaneously BID #1 Pen

FDA Prescription Simulation Responses (Aggregate Report)

215 People Received Study
71 People Responded

Study Name: Bynfezia Pen

Total	18	17	36	71

INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BEMFEZIA PEN	0	1	0	1
BENDEZIA 10	0	1	0	1
BENFEZIA PEN	0	3	0	3
BENFEZZIA PEN	0	1	0	1
BENSESSIA PEN	0	1	0	1
BENTHESIA 10	0	1	0	1

BENVEZIA 10	0	2	0	2
BENVEZIA PEN	0	4	0	4
BENZESSIA PEN	0	1	0	1
BENZEZIA PEN	0	1	0	1
BYMFEZIA	0	0	1	1
BYMFEZIA PEN	0	0	2	2
BYNBEZIA PEN	0	0	1	1
BYNFEZIA	0	0	3	3
BYNFEZIA PEN	18	0	27	45
BYNFEZIA PEN 100 MCG	0	0	1	1
BYRFEZIA PEN	0	0	1	1
DEXEZIA PEN	0	1	0	1

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

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.	Benzagel	58
2.	Benzac W	56
3.	Benzac AC	56
4.	Benzac	55

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:** Bynfezia Pen **Established name:** octreotide acetate **Dosage form:** Injection **Strength(s):** (b) (4) 2.8 ml (2.5 mg/mL) **Usual Dose:** 50 mcg/day -600 mcg/day in 2-4 divided doses	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**
5.	(b) (4) ***	64	This name pair has sufficient orthographic and phonetic differences.
6.	Benzefoam	62	This name pair has sufficient orthographic and phonetic differences.
7.	Dynafed	61	This name pair has sufficient orthographic and phonetic differences.
8.	Benefiber	59	This name pair has sufficient orthographic and phonetic differences.
9.	Benefix	59	This name pair has sufficient orthographic and phonetic differences.
10.	Benza	58	This name pair has sufficient orthographic and phonetic differences.
11.	Bifera	58	This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.
13.	10 Benzagel	58	This name pair has sufficient orthographic and phonetic differences.
14.	5 Benzagel	58	This name pair has sufficient orthographic and phonetic differences.
15.	Banflex	57	This name pair has sufficient orthographic and phonetic differences.

16.	Benzonate	57	This name pair has sufficient orthographic and phonetic differences.
17.	Bendeka	57	This name pair has sufficient orthographic and phonetic differences.
18.	Natazia	57	This name pair has sufficient orthographic and phonetic differences.
19.	Benz-All	56	This name pair has sufficient orthographic and phonetic differences.
20.	(b) (4) ***	56	Orthographically, the suffixes of this name pair are different (b) (4) giving the name pair different shapes when scripted. Phonetically, Bynfezia contains 4 syllables vs (b) (4) (b) (4) *** is stored only in procedural areas and in inpatient pharmacies that support procedural sedation. Pharmacies will dispense (b) (4) *** directly to the procedural care personnel because (b) (4) ** is administered only by healthcare professionals appropriately trained in procedural sedation who will monitor the patient for the duration of the procedure and administer additional doses to maintain sedation as needed.
21.	(b) (4) ***	56	(b) (4)

			(b) (4)
22.	Benziq	56	This name pair has sufficient orthographic and phonetic differences.
23.	Benzoin	56	This name pair has sufficient orthographic and phonetic differences.
24.	Bionafem	56	This name pair has sufficient orthographic and phonetic differences.
25.	Dynafreeze	56	This name pair has sufficient orthographic and phonetic differences.
26.	Benzaclin	55	This name pair has sufficient orthographic and phonetic differences.
27.	Benzashave	55	This name pair has sufficient orthographic and phonetic differences.
28.	Benzashave 10	55	This name pair has sufficient orthographic and phonetic differences.
29.	Benzashave 5	55	This name pair has sufficient orthographic and phonetic differences.
30.	Boniva	55	This name pair has sufficient orthographic and phonetic differences.
31.	Benzamycin	55	This name pair has sufficient orthographic and phonetic differences.
32.	Bonsity	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
33.	Benlysta	52
34.	Benzphetamine	50
35.	Benzilic Acid	50
36.	Dynapen	50
37.	Beta-Pinene	48
38.	Nifedipine	45
39.	Bydureon	44
40.	Byette	44
41.	Benzylparaben	43
42.	Amitiza	42
43.	Pfizerpen-A	42
44.	Pediaphen	42
45.	Gentacidin	42
46.	Pfizerpen	40
47.	Dimetane-Ten	39
48.	Pentostatin	36
49.	Epipen E Z Pen	35

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
50.	Sanfed A	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Banadyne	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
52.	Benzapen	58	International product marketed in numerous foreign countries.
53.	Benzie Pak	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
54.	Bentasil	57	International product formally marketed in Canada.
55.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found to be unacceptable (RCM 2016-11864916). An alternative name has not been submitted for this product.

No.	Name	POCA Score (%)	Failure preventions
56.	Benzarone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
57.	Benerva	56	International product marketed in numerous foreign countries.
58.	Bonjela	55	International product marketed in numerous foreign countries.
59.	Benserazide	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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

No.	Name	POCA Score (%)
60.	Fentazin	62
61.	Nifediac	62
62.	Convenia	58
63.	Zenzedi	58
64.	Kymfabi	57
65.	Fenbuzip	56
66.	Finzala***	56
67.	(b) (4) ***	56
68.	Nafazair	55
69.	Zinacef	55
70.	Mepsevii	50

[g] 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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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:	June 18, 2019
Application Type and Number:	NDA 213224
Product Name and Strength:	(b) (4) (octreotide acetate) injection, (b) (4) 2.8 ml (2.5 mg/mL) multi dose pen injector
Total Product Strength:	2.8 mL multi dose pen injector (calculated total strength: (b) (4))
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharmaceutical Industries (Sun Pharma)
Panorama #:	2018-30640144
DMEPA Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA
DMEPA Deputy Director:	Irene Z. Chan, PharmD, BCPS

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