CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-542Orig1s000

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 Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	December 1, 2011
Reviewer(s):	Manizheh Siahpoushan, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Zachary Oleszczuk, Pharm.D. Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RP.h. Division of Medication Error Prevention and Analysis
Drug Name and Strengths:	Viokace (Pancrelipase) Tablets 10,440 U.S.P. Units Lipase 39,150 U.S.P. Units Amylase 39,150 U.S.P. Units Protease And 20,880 U.S.P. Units Lipase 78,300 U.S.P. Units Amylase 78,300 U.S.P. Units Protease
Application Type/Number:	NDA 022542
Applicant/sponsor:	Axcan Pharma
OSE RCM #:	2011-3386

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

CONTENTS

1 INTRODUCTION

This review responds to a request from Axcan Pharma, dated September 29, 2011 for a safety and promotional re-assessment of the proposed proprietary name, Viokace (NDA 022542). The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Viokace, acceptable in OSE Review #2009-2129, dated January 21, 2010, OSE Review #2010-180, dated June 22, 2010, and OSE Review #2010-1827, dated October 15, 2010.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-2129 for the proposed proprietary name, Viokace. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded no new names thought to look similar to Viokace and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Viokace, as of September 29, 2011.

The Division of Gastroenterology Products did not have any concerns with the proposed name, Viokace, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective as noted in OSE Review #2009-2129.

3 CONCLUSIONS AND RECOMMENDATIONS

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

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. **OSE review #2009-2129 Proprietary Name Review of Viokace; Chan, Irene Z.**
2. **OSE review #2010-180 Proprietary Name Review of Viokace; Chan, Irene Z.**
3. **OSE review #2010-1827 Proprietary Name Review of Viokace; Chan, Irene Z.**
4. ***Drugs@FDA*** (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

   Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

5. ***USAN Stems*** (*http://www.ama-assnorg/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)*
   USAN Stems List contains all the recognized USAN stems.
6. ***Division of Medication Error Prevention and Analysis proprietary name 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.

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/s/

MANIZHEH SIAHPOUSHAN
12/01/2011

ZACHARY A OLESZCZUK
12/01/2011

CAROL A HOLQUIST
12/05/2011

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	October 15, 2010
Application Type/Number:	NDA 022542
Through:	Melina Griffis, RPh, Team Leader Denise Toyer, Pharm.D., Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Irene Z. Chan, Pharm.D., BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Viokace (Pancrelipase) Tablets 10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease 20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease
Applicant:	Axcan Pharma
OSE RCM #:	2010-1827

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CONTENTS

1 INTRODUCTION

This re-assessment of the proprietary name responds to a notification that NDA 022542 may be approved within 90 days. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Viokace, acceptable in OSE Review #2009-2129, dated January 21, 2010, and OSE Review #2010-180, dated June 22, 2010.

The Division of Gastroenterology Products did not have any concerns with the proposed name, Viokace, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective as noted in OSE Review #2009-2129.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-2129 for the proposed proprietary name, Viokace. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded no new names thought to look similar to Viokace and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Viokace, as of October 6, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Viokace, is not vulnerable to name confusion that can lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Viokace, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. **OSE review #2009-2129 Proprietary Name Review of Viokace; Chan, Irene Z.**
2. **OSE review #2010-180 Proprietary Name Review of Viokace; Chan, Irene Z.**
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4. ***USAN Stems (***http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml***)***
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/s/

IRENE Z CHAN
10/15/2010

MELINA N GRIFFIS
10/18/2010

CAROL A HOLQUIST on behalf of DENISE P TOYER
10/18/2010

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	June 22, 2010
To:	Donna Griebel, M.D., Director Division of Gastroenterology Products
Through:	Melina Griffis, RPh, Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Irene Z. Chan, Pharm.D., BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Viokace (Pancrelipase) Tablets 10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease 20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease
Application Type/Number:	NDA 022542
Applicant:	Axcan Pharma
OSE RCM #:	2010-180

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CONTENTS

1 INTRODUCTION

This re-assessment of the proprietary name responds to a notification that NDA 022542 may be approved within 90 days. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Viokace, acceptable in OSE Review #2009-2129, dated January 21, 2010.
The Division of Gastroenterology Products did not have any concerns with the proposed name, Viokace, and the Division of Drug Marketing, Advertising and Communications (DDMAC) found the name acceptable from a promotional perspective as noted in OSE Review #2009-2129.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-2129 for the proposed proprietary name, Viokace. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

The searches of the databases yielded no new names thought to look similar to Viokace and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Viokace, as of June 14, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Viokace, is not vulnerable to name confusion that can lead to medication errors nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Viokace, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. **OSE review #2009-2129 Proprietary Name Review of Viokace; Chan, Irene Z.**

2. ***Drugs@FDA (***http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm***)***
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3. ***USAN Stems (***http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml***)***
   USAN Stems List contains all the recognized USAN stems.

4. ***Division of Medication Error Prevention and Analysis proprietary name 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.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22542	ORIG-1	AXCAN PHARMA US INC	VIOKASE (PANCRELIPASE)UNCOATED TABLETS

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/s/

IRENE Z CHAN
06/22/2010

MELINA N GRIFFIS
06/23/2010

DENISE P TOYER
06/23/2010

CAROL A HOLQUIST
06/23/2010

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	January 21, 2010
To:	Donna Griebel, M.D., Director Division of Gastroenterology Products
Through:	Melina Griffis, RPh, Team Leader Denise Toyer, Pharm.D., Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Irene Z. Chan, Pharm.D., BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Viokace (Pancrelipase) Tablets 10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease 20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease
Application Type/Number:	NDA 022542
Applicant/Applicant:	Axcan Pharma
OSE RCM #:	2009-2129

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EXECUTIVE SUMMARY

Viokace is the proposed proprietary name for pancrelipase tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name Viokace conditionally acceptable for this product. The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

This review is in response to a request from Axcan Pharma dated October 30, 2009, for an assessment of the proposed proprietary name, Viokace, regarding potential name confusion with other proprietary or established drug names in the usual practice settings. The Applicant submitted an external study conducted by (b) (4) in support of their proposed proprietary name. The Applicant also submitted draft container labels, carton and insert labeling. These labels and labeling will be reviewed separately under OSE Review #2009-2130.

1.2 REGULATORY HISTORY

Viokase, Viokase 8, Viokase 16, and Viokase Powder have been available in the marketplace without an approved NDA since 1949. A Federal Register (FR) Notice dated April 20, 2004 notified manufacturers of pancreatic insufficiency products that FDA approval, via the submission of a new drug application (NDA), would be required by April 2008 (deadline has been extended to April 2010) for these products to remain in the US marketplace. In accordance to this FR notice, the manufacturer of Viokase submitted an NDA for this product on April 28, 2009.

As of the date of this review, it has been determined that all three ingredients, lipase, amylase, and protease, are active and will be included on labels and labeling with their respective strengths, even though current dosing practices are only based on the lipase component.

1.3 PRODUCT INFORMATION

Viokace, in combination with a proton pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis (b) (4). Viokace contains a combination of lipase, protease, and amylase; however, it is dosed in lipase units and will be available in two strengths: 10,440 UPS units of lipase and 20,880 USP units of lipase. Both strengths will be marketed in bottles of 100 tablets. Enzyme dosing should begin with 500 lipase units/kg of body weight per meal to a maximum of 2,500 lipase units/kg of body weight per meal (or less than or equal to 10,000 lipase units/kg of body weight per day). Usual dosing is 1 to 4 tablets by mouth with meals or as directed by the physician.

2 METHODS AND MATERIALS

Appendix A describes the general methods and materials used by the Division of Medication Error Prevention and Analysis (DMEPA) when conducting a proprietary name risk assessment for all proprietary names. Sections 2.1, 2.2, 2.3, and 2.4 identify specific information associated with the methodology for the proposed proprietary name, Viokace.

2.1 SEARCH CRITERIA

For this review, particular consideration was given to drug names beginning with the letter 'V' when searching to identify potentially similar drug names, as 75% of the confused drug names reported by the USP-ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2]

To identify drug names that may look similar to Viokace, the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (7 letters), upstrokes (2, capital letter 'V' and lower case letter 'k'), downstrokes (none), cross strokes (none), and dotted letters (1, lower case letter 'i'). Additionally, several letters in Viokace may be vulnerable to ambiguity when scripted (see Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Viokace.

When searching to identify potential names that may sound similar to Viokace, the DMEPA staff search for names with similar number of syllables (three), stresses (VI-o-kace, vi-O-kace, and vi-o-KACE), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary (see Appendix B). The Sponsor's intended pronunciation (vye' oh kase) was also taken into consideration, as it was included in the Proprietary Name Review Request. Furthermore, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA ADVERSE EVENT REPORTING SYSTEM (AERS)

Viokase tablets are currently marketed, therefore, DMEPA conducted a search of the FDA Adverse Event Reporting System (AERS) database on December 7, 2009, to identify medication errors involving Viokase.

The MedRA High Level Group Terms (HLGT) "Medication Errors" and "Product Quality Issues" were used as search criteria for Reactions. The search criteria used for Products was verbatim substance search "Vioka%". No date limitations were set.

The reports were manually reviewed to determine if a medication error occurred. Duplicate reports were combined into cases. The cases that described a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors. If a root cause was associated with the name of the product, the case was considered pertinent to this review. Those reports that did not describe a medication error or did not describe an error applicable to this review (e.g. errors related to accidental exposures, intentional overdoses, etc.) were excluded from further analysis.

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[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

[2] Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

2.3 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, the following inpatient medication order, outpatient and verbal prescription was communicated during the FDA prescription studies.

Figure 1. Viokace Study (conducted on November 23, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: Viokace 4 tablets po with meals	Viokace 4 tabs TID with meals dispense 180
Outpatient Prescription: Viokace 4 tabs TID c meals #180	

2.4 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

For this product, the Sponsor submitted an external evaluation of the proposed proprietary name. The Division of Medication Error Prevention and Analysis conducts an independent analysis and evaluation of the data provided, and responds to the overall findings of the assessment. When the external proprietary name risk assessment identifies potentially confusing names that were not captured in DMEPA's database searches or in the Expert Panel Discussion, these names are included in the Safety Evaluator's Risk Assessment and analyzed independently by the Safety Evaluator to determine if the potentially confusing name could lead to medication errors in usual practice settings.

After the Safety Evaluator has determined the overall risk associated with the proposed name, the Safety Evaluator compares the findings of their overall risk assessment with the findings of the proprietary name risk assessment submitted by the Sponsor. The Safety Evaluator then determines whether the Division's risk assessment concurs or differs with the findings. When the proprietary name risk assessments differ, the Division of Medication Error Prevention and Analysis provides a detailed explanation of these differences.

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The Expert Panel searches yielded a total of 11 names as having some similarity to the name Viokace; however, one of the names identified was Viokase 16. Viokase 16 will be considered under our evaluation of the name Viokase (see Appendix I). Another name identified, Viodine, is a foreign drug name and will not be evaluated. Therefore, DMEPA evaluated the remaining 9 names.

Seven of the nine names were thought to look like Viokace. These include Uni-Ace, Urokinase, Valhist, Varidase, (b) (4) Viorele, and Vitrase. One name, Viokase, was thought to both look and sound like Viokace. One name, Vioxx, was thought to sound like Viokace.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of November 12, 2009.

3.2 EXPERT PANEL DISCUSSION

The Expert Panel reviewed the pool of names identified by DMEPA staff (See Section 3.1 above) and noted no additional names thought to have orthographic or phonetic similarity to Viokace.

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

3.3 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

The AERS search conducted on December 7, 2009, yielded 2 cases. One case was excluded from further evaluation because it was a wrong drug error where two different medications had been accidentally dispensed in one bottle. There is no indication that name confusion was a contributing factor in this case.

The second case reported an error due to an order for Viokase that read "Viokase 8 tabs with meals TID." This order was clarified by the pharmacist to read "Viokase-8 three tablets with meals TID." The case identified confusion caused by the use of the suffix "8" in the proprietary name "Viokase 8". This error did not reach the patient.

3.4 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 21 practitioners responded in the prescription analysis studies. Seven of the participants interpreted the name correctly as "Viokace." Seven participants interpreted the name as "Viokase" with an "s" instead of a "c" in the suffix. The remainder of the responses misinterpreted the drug name or had more than one interpretation noted. Several misinterpretations occurred with the letter "k" being mistaken as "c" in the voice prescription studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.5 EXTERNAL STUDY

In the proposed name risk assessment submitted by the Applicant, (b) (4) identified and evaluated a total of 16 drug names thought to have some potential for confusion with the name Viokace: Altace, Amikacin, Betapace, Bioclate, Megace, Panokase, Velcade, Velosef, Viactiv, Viadur, Viokase, Vioxx, Viracept, Vitrase, Zincate, and Zycose. Of the names identified by (b) (4) three were also identified by DMEPA during the database searches: Viokase, Vioxx, and Vitrase. The remaining 13 names will be considered in the safety evaluator assessment.

3.6 COMMENTS FROM THE DIVISION OF GASTROENTEROLOGY PRODUCTS (DGP)

3.6.1 Initial Phase of Review

In a response to the OSE November 16, 2009 e-mail, the Division of Gastroenterology Products (DGP) did not have any preliminary concerns about the proposed proprietary name, Viokace.

3.6.2 Midpoint of Review

On December 9, 2009 DMEPA notified the Division of Gastroenterology Products (DGP) via e-mail that we had no objections to the proposed proprietary name Viokace. Per e-mail correspondence from the

Division of Gastroenterology Products on December 17, 2009, they indicated there were no objections to our assessment of the proposed proprietary name, Viokace.

3.7 SAFETY EVALUATOR RISK ASSESSMENT OF PROPOSED PROPRIETARY NAME

The Expert Panel identified a total of nine names as having some similarity to Viokace. Thirteen names were identified by (b) (4) the external consultant. Independent searches by the primary Safety Evaluator resulted in identification of 13 additional names which were thought to look or sound similar to Viokace and represent a potential source of drug name confusion. Two of the 13 names, Viokase 8 and Viokase Powder, will be considered under our evaluation of the name "Viokase," which was previously identified in section 3.1 above. Therefore, 11 additional names will be evaluated.

All 11 names were thought to have look-alike similarities to Viokace: Neofrin, Neotrace-4, (b) (4) Ventavis, Vertavis, Viaderm-KC, Viadrone, Victoza, Vioday, Visken, and (b) (4)

After combining the names identified by the Expert Panel, independent searches, and the external study, a total of 33 names were evaluated for their similarity to the proposed name.

4 DISCUSSION

4.1 PROMOTIONAL REVIEW

DDMAC did not find the name Viokace promotional. DMEPA and the Division of Gastroenterology Products concurred with this assessment.

4.2 SAFETY REVIEW

A search of the FDA AERS database was conducted and identified one case where the name Viokase was identified as a cause for error. The case specified the suffix "8" in the name "Viokase 8" as the cause for error. Because the Applicant has submitted a new name, Viokace, which does not contain a suffix, we do not believe this case is relevant to our review.

DMEPA did not identify other factors besides names with potential similarity to Viokace that would render the name unacceptable.

In total, 33 names were identified as potential sources of confusion and evaluated by DMEPA. Thirteen of the 33 names lacked convincing orthographic and/or phonetic similarity to the proposed proprietary name Viokace and were not evaluated further (see Appendix D).

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary name could potentially be confused with the remaining 20 names and lead to medication errors. This analysis determined that the name similarity between Viokace was unlikely to result in medication errors with any of the 20 products for the reasons presented in Appendices E through I. This finding was consistent with and supported by an independent risk assessment of the proprietary name submitted by the Applicant.

5 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Viokace, is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Viokace, for this product at this time. Our analysis is consistent with the external risk assessment conducted by (b) (4) that was provided by the Applicant. The Applicant will be notified via letter.

5.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Viokace, and have concluded that it is acceptable.

The proposed proprietary name must be re-reviewed 90 days before approval of the NDA.

If any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

6 REFERENCES

1. Micromedex Integrated Index (http://csi.micromedex.com)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products.

4. AMF Decision Support System [DSS]

DSS is a government database used to track individual submissions and assignments in review divisions.

5. Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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7. Electronic online version of the FDA Orange Book (http://www.fda.gov/cder/ob/default.htm)

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)

The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

12. Stat!Ref (www.statref.com)

Stat!Ref contains full-text information from approximately 30 texts; it includes tables and references. Among the database titles are: Handbook of Adverse Drug Interactions, Rudolphs Pediatrics, Basic Clinical Pharmacology, and Dictionary of Medical Acronyms Abbreviations.

13. USAN Stems (http://www.ama-assn.org/ama/pub/category/4782.html)

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

15. Lexi-Comp (www.lexi.com)

Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

16. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. 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. [3]

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources to identify names with orthographic and phonetic similarity and hold a Center for Drug Evaluation and Research (CDER) Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name. DMEPA staff also conducts internal CDER prescription analysis studies. When provided, DMEPA considers external prescription analysis study results and incorporate into the overall risk assessment.

The Safety Evaluator assigned to the Proprietary Name Risk Assessment is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name, and focuses on the avoidance of medication errors.

FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. [4] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

In addition, the product characteristics provide the context for the verbal and written communication of the drug names and can interact with the orthographic and phonetic attributes of the names to increase the risk of confusion when there is overlap or, in some instances, decrease the risk of confusion by helping to differentiate the products through dissimilarity. Accordingly, the DMEPA staff considers the product characteristics associated with the proposed drug throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[5] DMEPA provides the product characteristics considered for this review in section one.

The Division of Medication Error Prevention and Analysis considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA also compares the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products

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

[4] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

[5] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

because similarly in spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. DMEPA staff also examines the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly and even dissimilarly spelled drug name pairs to appear very similar to one another. The similar appearance of drug names when scripted has led to medication errors. The DMEPA staff applies expertise gained from root-cause analysis of such medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details). In addition, the DMEPA staff compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. If provided, DMEPA will consider the Applicant's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Applicant has little control over how the name will be spoken in clinical practice.

Table 1. Criteria used to identify drug names that look- or sound-similar to a proposed proprietary name.

Type of similarity	**Considerations when searching the databases**		
	Potential causes of drug name similarity	*Attributes examined to identify similar drug names*	*Potential Effects*
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication • Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name Upstrokes Down strokes Cross-stokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	• Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	• Names may sound similar when pronounced and lead to drug name confusion in verbal communication

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a

variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA staff conducts searches of the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name using the criteria outlined in Section 2.1. Section 6 provides a standard description of the databases used in the searches. To complement the process, the DMEPA staff use a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, the DMEPA staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel.

2. CDER Expert Panel Discussion

DMEPA conducts an Expert Panel Discussion to gather CDER professional opinions on the safety of the proposed product and the proposed proprietary name. The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the DMEPA staff to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend the addition of names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

3. FDA Prescription Analysis Studies

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 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 the 123 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 send their interpretations of the orders via e-mail to DMEPA.

4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary

name and 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 DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or 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 concur/not concur with DMEPA's final decision.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, conducts a Failure Mode and Effects Analysis, and provides an overall risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[6] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Section one. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not

[6] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Risk Assessment:

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA is likely to recommend that the Applicant select an alternative proprietary name and submit the alternate name to the Agency for DMEPA to review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Applicant with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant. However, the safety concerns set forth in criteria a through e are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), Joint Commission on Accreditation of Hospitals (JCOAH), and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and a preventable source of medication error that, in many instances, the Agency and/or Applicant can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name

confusion. Applicants have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Applicant and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Applicants' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval (see Section 4 for limitations of the process).

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in name, Viokace	Scripted may appear as	Spoken may be interpreted as
Capital 'V'	N, R, U	B
lower case 'i'	e, l	
lower case 'o'	a, e, r, s, u	any vowel
lower case 'k'	d, l, t	c
lower case 'a'	ce, ci, cl, e, o, u	any vowel
lower case 'c'	a, u	s
lower case 'e'	a, e, i, l, o	any vowel

Appendix C: FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Viokace	Viokase (?viokace)	Viocase
Viokace	Viokace	Viokase
Viokase	Viokase	Viocase
Viokace or Ziokace or Liokace	Viokase	Vidocase
Viokace	Viokace	Viokase
Viokace	Viokase	Viocase
Viokace		Viokase
Viakace		

Appendix D: Drug names that lack convincing orthographic and/or phonetic similarities

Name	Similarity to Viokace
Valhist	Look alike
Viorele	Look alike
Vioxx	Sound alike
Altace	(b) (4)
Amikacin	
Betapace	
Megace	
Panokase	
Velcade	
Velosef	
Viracept	
Zincate	
Zycose	

Appendix E: Herbal Product or Supplement with no overlap in strength or frequency

Name	Similarity to Viokace	Product Description
Viactiv	Look alike	Multivitamin or calcium supplement soft chews taken once or twice daily
Viadrone	Look alike	Oral capsules containing Saw Palmetto and Maca root standardized and Korean Ginseng and Hawthorne berry and Ginkgo Biloba and Pumpkin seeds and Rhodiola Rosea and Tienchi Ginseng and Schisandra berry and Lycium fruit and Cistache and Astragalus and Poria Sclerotium and Passion Flower and Chinese Yam and Avena Sativa and Polygonum Multiflorum. This product is marketed for erectile dysfunction and is used up to 48 hours before sexual intercourse.

Vioday	Look alike	Multivitamin tablet used as a once daily supplement and available over the counter (multiple generic products are available)

Appendix F: Names of products withdrawn from the market or not marketed in the U.S.

Proprietary Name	Similarity to Viokace	Status
Urokinase (established name for Kinlytic)	Look alike	Product discontinued with no generics available
Varidase (streptokinase and streptodornase and thimerosal)	Look alike	No longer marketed in the U.S. and no generic products available in U.S.
Viadur (leuprolide acetate)	Look alike	Product discontinued with no therapeutic equivalents available
Vertavis (veratrum viride)	Look alike	Product discontinued with no generic products available
Visken (pindolol)	Look alike	Product withdrawn from market and no therapeutic equivalents available

Appendix G: Unapproved proprietary names

Proprietary Name	Similarity to Viokace	Status and Date
(b) (4)		

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

Appendix H: Potential confusing names with no overlap in strength and other multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Viokace	Strength	Usual Dose	Differentiating product characteristics (Viokace vs. Product)
Viokace (pancrelipase) Tablets	**N/A**	**10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease** **20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease**	**1 – 4 tablets with meals or as directed by physician**	**N/A**
Vitrase (hyaluronidase) Injectable	Look alike	200 units/vial	Absorption and Dispersion of Injected Drugs or Solution: Typically 150 Units	Route of Administration: *Oral vs. subcutaneous injection or hypodermoclysis* Dosage Form: *Tablets vs. injectable* Frequency: *Three times daily vs. as needed*
Bioclate (antihemophilic factor) Lyophilized Powder for Injection	Sound alike	250 IU/bottle, 500 IU/bottle, 1000 IU/bottle	Varying dose based on required post-infusion AHF activity in the blood (frequent assays required)	Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablets vs. injection* Duration of Therapy: *Long term therapy vs. acute or perioperative treatment*
Neofrin (phenylephrine) Ophthalmic Solution	Look alike	2.5%, 10%	One drop in affected eye(s) 30 to 60 minutes before surgery or prior to eye examination	Route of Administration: *Oral vs. Ophthalmic* Dosage Form: *Tablets vs. ophthalmic solution* Frequency: *Three times daily vs. one time prior to eye surgery or exam*
Neotrace-4 (zinc sulfate, cupric sulfate, manganese sulfate, and chromic chloride) Injectable	Look alike	6.6 mg/0.39 mg/ 77 mcg/4.36 mcg per mL	Variable dosing depending on patient's levels	Route of Administration: *Oral vs. intravenous infusion* Dosage Form: *Tablets vs. injectable* Frequency: *Three times daily vs. continuous intravenous infusion as part of total parenteral nutrition (TPN)*
Ventavis (iloprost) Solution	Look alike	10 mcg/mL, 20 mcg/mL	2.5 mcg to 5 mcg six to nine times per day (no more than once every 2 hours) during	Route of Administration: *Oral vs. inhalation* Dosage Form: *Tablets vs. solution*

Product name with potential for confusion	Similarity to Viokace	Strength	Usual Dose	Differentiating product characteristics (Viokace vs. Product)
Viokace (pancrelipase) Tablets	**N/A**	**10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease** **20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease**	**1 – 4 tablets with meals or as directed by physician**	**N/A**
			waking hours according to individual need and tolerability	Frequency: *Three times daily vs. six to nine times per day*
Viaderm-KC (nystatin and triamcinolone) Cream	Look alike	0.1%	Apply sparingly as a thin film to the affected skin twice daily, morning and evening	Route of Administration: *Oral vs. topical* Dosage Form: *Tablets vs. cream* Frequency: *Three times daily vs. twice daily*
Victoza*** (liraglutide) Injectable	Look alike	18 mg/3 mL	1.2 to 1.8 mg once daily. Dose must be individualized.	Route of Administration: *Oral vs. subcutaneous injection* Dosage Form: *Tablets vs. injectable* Frequency: *Three times daily vs. once daily*

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

Appendix I: Potentially confusing names that are unlikely to cause medication errors

Proposed Name: **Viokace (pancrelipase) Tablets**	**Strength:** **10,440 U.S.P. Units lipase/ 39,150 U.S.P. Units amylase/ 39,150 U.S.P. Units protease** **20,880 U.S.P. Units lipase/ 78,300 U.S.P. Units amylase/ 78,300 U.S.P. Units protease**	**Usual Dose:** **1 – 4 tablets with meals or as directed by physician**
Failure Mode: Name confusion	**Causes (can be multiple)**	**Prevention of Failure Mode**
Viokase (pancrelipase) Tablets and Powder **Strength:** 8,000 U.S.P. Units lipase/ 30,000 U.S.P. Units amylase/ 30,000 U.S.P. Units protease (Viokase 8) 16,000 U.S.P. Units lipase/ 60,000 U.S.P. Units amylase/ 60,000 U.S.P. Units protease (Viokase 16) 16,800 U.S.P. Units lipase/ 70,000 U.S.P. Units amylase/ 70,000 U.S.P. Units protease in each 0.7 g (1/4 teaspoonful) (Viokase Powder) **Usual Dose:** Variable dose taken with meals or as directed by physician	**Orthographic Similarities:** Both names are nearly identical with only a "c" vs. an "s" in the suffix differentiating between the two names **Phonetic Similarities:** Both names begin with "viok"; both names contain three syllables; both "ace" and "ase" are pronounced identically **Overlap in Route of Administration:** Both are given orally **Overlap in Frequency:** Both are dosed with meals or as directed by physician	**Rationale:** Viokase is the same product in this review undergoing FDA approval and will be marketed under "Viokace" once approved. Viokase will be marketed with the stand-alone proprietary name "Viokace" without modifiers when it is approved. In order to meet current standards, the proposed Viokace labels and labeling will be revised to accurately reflect the USP units for all three enzymes of the active ingredient, and to correctly reflect the amount of USP units contained in each capsule. While there may be a period of overlap when both products are available in the market, it is anticipated that the product labels and labeling will be sufficient to distinguish the two products during this overlap period. In addition, these products do not have overlapping marketing strengths. Therefore, if a provider were to write a prescription for "Viokase" instead of "Viokace," he or she would still have to write the strength since these are not single strength products. Any discrepancies in ordered strength or missing strength selection would need to be clarified with the provider before dispensing and administering.

(b) (4)		
Uni-Ace (acetaminophen) Tablets, Capsules, or Oral Solution **Strength:** 325 mg, 500 mg, 100 mg/mL **Usual Dose:** Up to 1000 mg per dose every 6 hours. Max of 4000 mg per day. For children, weight dependant dosing	**Orthographic Similarities:** "U" in Uni-Ace can look like a "V." Both names end in the suffix "ace." When scripted out, both names appear similar in length. **Overlap in Route of Administration:** Both are given orally.	Differences in product characteristics minimize the likelihood of medication error in the usual practice setting. **Rationale:** Uni-Ace and Viokace do not have any strength overlap. Uni-Ace is available as 325 mg, 500 mg, or 100 mg/mL whereas Viokace is available as 10,440 USP Units or 20,880 USP Units (typically dosed by lipase units). There is also no overlap in the usual dose for these two products. In addition, Uni-Ace is an over-the-counter product that is not typically dispensed pursuant to a prescription.

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22542	ORIG-1	AXCAN PHARMA US INC	VIOKASE (PANCRELIPASE)UNCOATED TABLETS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

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