CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202344Orig1s000

PROPRIETARY NAME REVIEW(S)

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

Proprietary Name Review--Final

Date:	February 9, 2012
Reviewer:	Chi-Ming Tu, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Todd Bridges, RPh Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name and Strength:	Binosto (Alendronate Sodium) Effervescent Tablets, 70 mg
Application Type/Number:	NDA 202344
Applicant:	EffRx Pharmaceuticals SA
OSE RCM #:	2011-4271

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Binosto is written in response to the anticipated approval of this NDA 202344 within 90 days from the date of this review. DMEPA found the proposed name, Binosto, acceptable in OSE Review #2011-2383 dated September 7, 2011 and OSE Review #2011-3808 dated November 7, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches 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. For this review we used the same search criteria described in OSE Review #2011-2383. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded 1 new name (Picato) thought to look similar to Binosto and represent a potential source of drug name confusion. Failure mode and effects analysis was applied to determine if the proposed proprietary name could potentially be confused with Picato and lead to medication errors. This analysis determined that the name similarity between Binosto and the identified name was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of January 26, 2012. The Office of Prescription Drug Promotion (OPDP) re-reviewed the proposed name on December 18, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Binosto, did not identify any vulnerabilities that would result in medication errors nor is the name considered promotional, thus, DMEPA has no objection to the proprietary name, Binosto, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA 202344 is delayed beyond 90 days from the date of this review, the Division of Reproductive and Urologic Products (DRUP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Maria Wasilik, OSE project manager, at 301-796-0567.

4 REFERENCES

1. OSE Reviews

Tu, C; OSE Review #2011-2383, Proprietary Name Review for Binosto. September 7, 2011.

Tu, C; OSE Review #2011-3808, Proprietary Name Review - Final for Binosto. November 7, 2011.

2. 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.

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

USAN Stems List contains all the recognized USAN stems.

4. Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

Appendix A: FMEA Table.

Proposed Name: Binosto (alendronate sodium)	**Strength/ Dosage Form: 70 mg Effervescent Tablet**	**Usual Dosage: Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly**
	Failure Mode	**Prevention of Failure Mode**
Picato (Ingenol mebutate) Gel, topical: 0.015% and 0.05% Actinic keratosis: (face and scalp) apply 0.015% to the affected area once daily for 3 consecutive days; (trunk and extremities) apply 0.05% to the affected area once daily for 2 consecutive days.	Orthographic similarities: Both names begin with similar letters (P vs. B), contain the same letter (i) in the second position, and end with the same letters (to). Both names contain similar number of letters (6 vs. 7).	Picato is available in multiple strengths so a specific strength is needed to dispense the drug, thus providing differentiating product characteristics from Binosto. Additionally, the strengths of Picato (0.015% and 0.05%) do not overlap with the strength of Binosto (70 mg). The dose of Picato is "thin film/layer" vs. the dose of Binosto is 1 effervescent tablet. The dosing frequency of Picato is once daily for 2 or 3 consecutive days vs. the dose of Binosto is once weekly.

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/s/

CHI-MING TU
02/09/2012

TODD D BRIDGES
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02/09/2012

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

Proprietary Name Review--Final

Date:	November 7, 2011
Reviewer:	Chi-Ming (Alice) Tu, PharmD Division of Medication Error Prevention and Analysis
Team Leader	Todd Bridges, RPh Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh Division of Medication Error Prevention and Analysis
Drug Name:	Binosto (Alendronate Sodium) Effervescent Tablets, 70 mg
Application Type/Number:	NDA 202344
Applicant/sponsor:	EffRx Pharmaceuticals SA
OSE RCM #:	2011-3808

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TABLE OF CONTENTS

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Binosto, is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, *Binosto,* acceptable in OSE Review 2011-2383 dated September 7, 2011.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches 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. For this review we used the same search criteria described in OSE Review 2011-2383. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. The searches of the databases yielded no new names thought to look or sound similar to Binosto and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of October 7, 2011. DDMAC re-reviewed the proposed name on October 13, 2011 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Binosto, did not identify any vulnerability that would result in medication errors nor is the proposed proprietary name considered promotional. Thus, DMEPA has no objection to the proprietary name, Binosto, 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 Reproductive and Urologic Products (DRUP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Maria Wasilik, OSE project manager, at 301-796-0567.

4 REFERENCES

1. OSE Review

Tu, C. OSE Review #2011-2383: Proprietary Name Review for Binosto. September 7, 2011.

2. 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.

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

USAN Stems List contains all the recognized USAN stems.

4. Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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/s/

CHI-MING TU
11/07/2011

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11/07/2011

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11/08/2011

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

Proprietary Name Review

Date:	September 7, 2011
Reviewer(s):	Chi-Ming (Alice) Tu, PharmD, Safety Evaluator Division of Medication Error Prevention and Analysis
Team Leader	Carlos M. Mena-Grillasca, RPh, Team Leader Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
Drug Name(s):	Binosto (Alendronate Sodium) Effervescent Tablets, 70 mg
Application Type/Number:	NDA 202344
Applicant/sponsor:	EffRx Pharmaceuticals
OSE RCM #:	2011-2383

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CONTENTS

1 INTRODUCTION

This review evaluates the proposed proprietary name, Binosto, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY INFORMATION

Binosto (Alendronate sodium) Effervescent Tablets was submitted as a 505(b)(2) application on June 21, 2011. The reference listed drug (RLD) is Fosamax (Alendronate Sodium) Tablets. Binosto is the second proposed proprietary name for this product. The first proposed proprietary name, Steovess, was found unacceptable by DMEPA in OSE Review #2011-2601, dated May 2, 2011.

1.2 PRODUCT INFORMATION

Binosto (Alendronate Sodium) Effervescent Tablets, 70 mg, is a bisphosphonate for the treatment of osteoporosis in postmenopausal women, and for the treatment to increase bone mass in men with osteoporosis. The recommended dose is one 70 mg effervescent tablet once weekly. The effervescent tablet should be dissolved in approximately half a glass of plain room temperature water (4 oz.), stir for 10 seconds after the effervescence stops, and then drink the solution. Binosto should be taken at least 30 minutes before the first food, beverage, or medication of the day. After taking the drug, patients should not lie down for at least 30 minutes and until after food. Binosto will be supplied in cartons containing either 4 or 12 unit of use blister strips. Binosto should be stored at 20°C to 25°C in the original blister package until use.

The RLD Fosamax (Alendronate Sodium) Tablets differs from Binosto in that Fosamax tablets should be swallowed whole with a full glass of water. In addition, Fosamax is available in multiple strengths and dosage forms: 5 mg, 10 mg, 35 mg, 40mg, and 70 mg tablets; and 70 mg/75 mL oral solution.

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

2 RESULTS

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Reproductive and Urologic Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The August 4, 2011 United States Adopted Name (USAN) stem search identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The proposed proprietary name is comprised of a single word. There are no components within this word that can contribute to medication errors.

2.2.4 *FDA Name Simulation Studies*

Thirty-five practitioners participated in DMEPA's prescription studies. None of the responses overlapped with other drug names. Seventeen participants interpreted the proposed proprietary name correctly as "Binosto." Common misinterpretations are the letter "D" for "B" (n=10) in the voice prescription, and the letter "e" for "i" in both the written medication order (n=2) and the voice prescription (n=6). See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 *Comments from Other Review Disciplines*

In response to the OSE, June 30, 2011 e-mail, the Division of Reproductive and Urologic Products (DRUP) did not have any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.6 *Failure Mode and Effects Analysis of Similar Names*

Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Binosto (see Appendix B). These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		Look Similar		Look Similar	
Name	***Source***	***Name***	***Source***	***Name***	***Source***
					(b) (4)
Benefix	EPD	Brontex	EPD	Minocin	Primary Reviewer
Benzotic	EPD	Buminate	EPD	Prezista	EPD
Berinert	EPD	Diocto	EPD	Renvela	EPD
Berdoz	EPD	Genaton	Primary Reviewer	Rescula	Primary Reviewer
Berotec	EPD	Kemstro	Primary Reviewer	Revatio	EPD
					(b) (4)
Boniva	EPD	Menest	Primary Reviewer		

Our analysis of the 23 names contained in Table 1 considered the information obtained in the previous sections along with the product characteristics. We determined the 23 names will not pose a risk for confusion as described in Appendices D and E.

DMEPA communicated these findings to the Division of Reproductive and Urologic Products (DRUP) via e-mail on August 4, 2011. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Reproductive and Urologic Products (DRUP) on August 12, 2011, they stated they have "no objection to the name," Binosto.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name is acceptable from both a promotional and safety perspective. However, 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.

The proposed proprietary name, Binosto, must be re-reviewed if the NDA approval is beyond 90 days from the signature date of this review.

If you have further questions or need clarifications, please contact Maria Wasilik, OSE project manager, at 301-796-0567.

4 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. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***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.

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. ***Access Medicine*** *(www.accessmedicine.com)*

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

13. ***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.

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 promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by DDMAC. DDMAC evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. DDMAC provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

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. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

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. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA 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.[2] The product characteristics considered for this review appears in Appendix B1 of this review.

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA 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. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing 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).

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*
	Similar spelling	Identical prefix	• Names may appear similar

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

Look-alike		Identical infix Identical suffix Length of the name Overlapping product characteristics	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/Similar shape Upstrokes Down strokes Cross-strokes 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, DMEPA 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 searches 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. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses 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, DMEPA reviews 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. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). 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). We also consider input from other review disciplines (OND, ONDQA/OBP). 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 database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional 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 Simulation 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/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.

4. 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 DDMAC'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.

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, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their 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.[3] 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 Appendix B1 of this review. 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***

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

practice setting? And Are there any components of the name that may function as a source of error beyond sound/look-alike"

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 or because of some other component of the name. 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 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.

Moreover, 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 Overall 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 but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

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 generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for 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 Sponsor 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/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading 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 preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

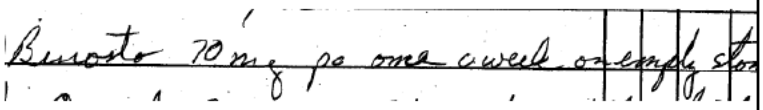
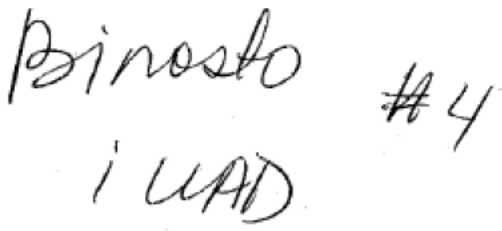
Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the past but at great financial cost to the Sponsor 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 Sponsors' 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.

Appendix B: Letters with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Binosto	Scripted may appear as	Spoken may be interpreted as
B	B, D, G, L, P, R	D, M, P, V
b	d, h, k, l, li, le	d, m, p, v
i	Any vowel	Any vowel
n	r, s, u, v	m
o	Any vowel	Any vowel
s	g, r, v, z	x, z
t	e, f, r, x	d

Appendix C: Prescription Simulation Samples and Results

Figure 1. Binosto Study (Conducted on July 15, 2011)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: 	Binosto Dispense quantity is 4 Direction is use as directed
Outpatient Prescription: 	

FDA Prescription Simulation Responses.

Inpatient Medication Order (n=12)	VOICE Prescription (n=14)	Outpatient Prescription (n=9)
BENORTO (1)	BENOSTOL (1)	BINOSTO (8)
BENOSTO (1)	BENOSTOW (1)	BINOSTO #4 (1)
BINORTO (1)	BINOSTO (2)	
BINOSTA (1)	DENOSTO (4)	
BINOSTO (6)	DINOSTO (4)	
BISSOSTO (2)	DINOSTOW (2)	

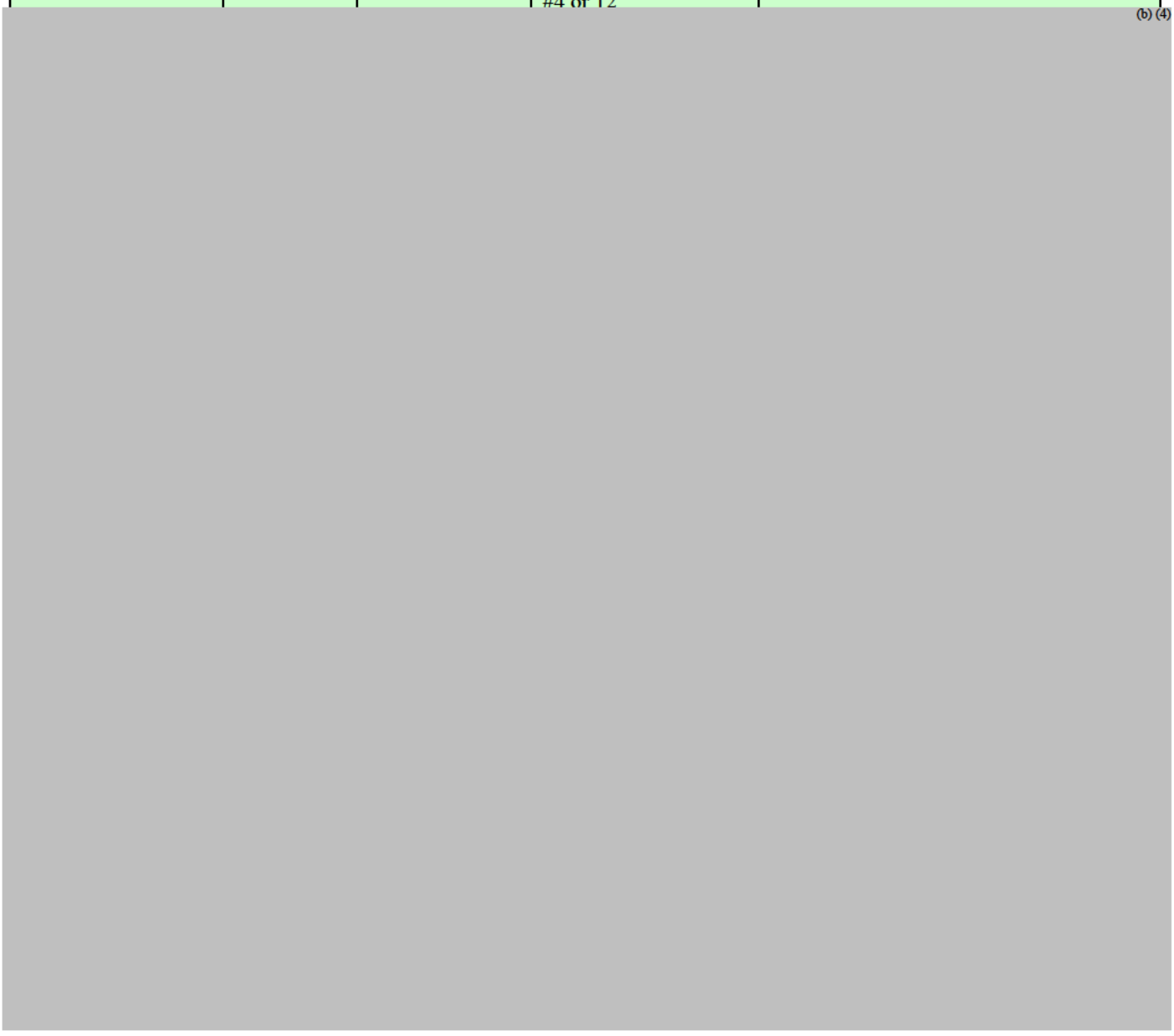
Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

Proprietary Name	Active Ingredient	Similarity to Binosto	Failure preventions
Berdoz	Cyanocoba-lamin, Vitamin B12	Look	Name lacking orthographic similarity to Binosto.
Berotec	Fenoterol HBr	Look	Name identified in Facts & Comparisons. Per Facts & Comparisons, the product is available outside the United States. The name was not found on Drugs@FDA or Lexi-Comp.
Rescula	Unoprostone Isopropyl	Look	Brand product discontinued with no generic available per Drugs@FDA and Orange Book.

Appendix E: Risk of medication errors due to product confusion minimized by dissimilarity of the names and/ or use in clinical practice for the reasons described.

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a

(b) (4)



Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
Benefix (factor IX)	Look	Injection, powder for reconstitution: ~250 international units, ~500 international units, ~1000 international units, ~2000 international units	<u>Adult</u> Primary prophylaxis: 25 to 40 international units/kg intravenous infusion twice weekly, or 40 to 100 international units/kg intravenous infusion two to three times weekly Hemorrhage: Dose = body weight (in kg) x desired factor IX level increase (as %) x 1.3 international units/kg, intravenous infusion <u>Pediatric less than 15 years of age</u> Dose = body weight (in kg) x desired factor IX level increase (as %) x 1.4 international units/kg, intravenous infusion Individualized based on severity of factor IX deficiency, extent and location of bleeding, and clinical status of patient	Strength: single strength (70 mg) vs. multiple strengths (~250, ~500, ~1000, ~2000 international units) Dose: 1 effervescent tablet or 70 mg vs. 1800 to 2880 international units (based on the 72 kg average adult weight) Dosage Form: effervescent tablet vs. injection Frequency: once weekly vs. two to three times weekly Orthographic Differences: Benefix contains the letter "x" at the end of the name, which provides orthographic differentiation from Binosto.
Berinert (C1 inhibitor, human)	Look	Injection, powder for reconstitution: 500 units	20 units/kg intravenous injection at a rate of 4 mL/minute for acute abdominal or facial attacks of hereditary angioedema in adult and adolescent patients	Dosage Form: effervescent tablet vs. injection Dose: 1 effervescent tablet or 70 mg vs. 1440 units (based on the 72 kg average adult weight) Frequency: once weekly vs. one time use for acute attack

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
Benzotic (antipyrine/benzo-caine)	Look	Solution, otic: 5.4%/1.4%	Instill 2 to 4 drops to the affected ear 3 to 4 times daily, or up to once every 1 to 2 hours	Dose: 1 effervescent tablet or 70 mg vs. 2 to 4 drops Route of administration: oral vs. otic Frequency: once weekly vs. 3 to 4 times daily, or up to once every 1 to 2 hours Dosage Form: effervescent tablet vs. otic solution
[redacted]				(b) (4)
Boniva (ibandronate)	Look	Injection, Solution: 1 mg/mL	3 mg intravenous injection every 3 months	Dose: 1 effervescent tablet or 70 mg vs. 3 mg Route of administration: oral vs. intravenous injection Frequency: once weekly vs. every 3 months Dosage Form: effervescent tablet vs. injection Other: Boniva is marketed in two different dosage formulations: injection and tablet, and the tablet dosage formulation is available in two strengths. Thus, either the strength, dosage formulation or the route of administration must be scripted on the prescription (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.

Product name with potential for confusion	**Similarity to Binosto**	**Dosage Form/ Strength**	**Usual Dose (if applicable)**	**Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described**
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
		Tablet: 2.5 mg and 150 mg	2.5 mg by mouth once daily, or 150 mg by mouth once a month	Strength: single strength (70 mg) vs. multiple strengths (2.5 mg and 150 mg) Frequency: once weekly vs. once daily or once a month Other: same as above.
Bosentan Bosentan is the established name for Tracleer. Tracleer was approved on November 20, 2001; no generic available as of July 15, 2011.	Look	Tablet: 62.5 mg and 125 mg	Adults or pediatric greater than 12 years old Less than 40 kg: 62.5 mg by mouth twice daily Greater than or equal to 40 kg: 125 mg by mouth twice daily	Strength: single strength (70 mg) vs. multiple strengths (62.5 mg and 125 mg) Frequency: once weekly vs. twice daily Orthographic Differences: Binosto contains a dotted letter "i" that is not seen in Bosentan.

Product name with potential for confusion	**Similarity to Binosto**	**Dosage Form/ Strength**	**Usual Dose (if applicable)**	**Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described**
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
Brontex (codeine/guaifene-sin)	Look	Tablet: 10 mg/ 300 mg	<u>Adult</u> 10 to 20 mg of codeine component by mouth every 4 to 6 hours as needed, do not exceed 120 mg codeine/day and 2.4 g guaifenesin/day. <u>Children 6 to 12 years of age</u>: 5 to 10 mg of codeine component by mouth every 4 to 6 hours as needed, do not exceed 60 mg codeine/day and 1.2 g guaifenesin/day. <u>Children 2 to 5 years of age:</u> 2.5 to 5 mg of codeine component by mouth every 4 to 6 hours as needed, do not exceed 30 mg codeine/day and 600 mg guaifenesin/day.	Frequency: once weekly vs. every 4 to 6 hours as needed Orthographic Differences: Binosto contains a dotted letter "i" that is not seen in Brontex. In addition, Brontex contains the letter "x" at the end of the name, which provides orthographic differentiation from Binosto. Other: Brontex is marketed in two different dosage formulations: oral solution and tablet. Thus, either the strength or dosage formulation must be indicated on the prescription (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.
		Solution, oral: 2.5 mg/75 mg per 5 mL	Same as above	Dose: 1 effervescent tablet or 70 mg vs. # mL or # teaspoon Frequency: once weekly vs. every 4 to 6 hours as needed Orthographic Differences: same as above Other: same as above
Buminate (albumin)	Look	Injection, solution: 5%, in 250 mL and 500 mL	Hypovolemic shock: 250 to 500 mL for adults and 12 to 20 mL/kg for children	Strength: single strength (70 mg) vs. multiple strengths (5% and 25%) Dose: 1 effervescent tablet or 70 mg vs. # mL

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
		Injection, solution: 25%, in 20, 50, and 100 mL	Burns: 500 mL intravenous infusion within the first 24 hours following burns Hypoalbuminemia: body albumin compartment should be calculated to be 80 to 100 mL/kg of body weight, not to exceed 2 g of albumin per kg of body weight Hypovolemic shock: 100 to 200 mL for adults and 2.5 to 5 mL/kg for children Burns: dose should be determined according to the patient's condition and response to treatment, administered within the first 24 hours following burns Hypoalbuminemia: body albumin compartment should be calculated to be 80 to 100 mL/kg of body weight, not to exceed 2 g of albumin per kg of body weight Hemolytic disease of the newborn: 1 g/kg intravenous infusion	Route of administration: oral vs. intravenous infusion Frequency: once weekly vs. as needed or immediately Dosage Form: effervescent tablet vs. injection

Product name with potential for confusion	**Similarity to Binosto**	**Dosage Form/ Strength**	**Usual Dose (if applicable)**	**Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described**
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
Diocto (docusate) Over-the-counter product	Look	Liquid, oral: 150 mg/15 mL Syrup, oral: 60 mg/15 mL	<u>Adult</u> 50 to 500 mg by mouth in one to four divided doses per day <u>Pediatric</u> Less than 3 years old: 10 to 40 mg by mouth in one to four divided doses per day 3 to 5 years old: 20 to 60 mg by mouth in one to four divided doses per day 6 to 12 years old: 40 to 150 mg by mouth in one to four divided doses per day	Strength/ Dosage Form: single strength and dosage form (70 mg effervescent tablet) vs. specific strength for each dosage form (150 mg/15 mL liquid or 60 mg/15 mL syrup) Dose: 1 effervescent tablet or 70 mg vs. # mL Frequency: once weekly vs. one to four times daily
Genaton (Liquid: aluminum hydroxide/ magnesium carbonate Tablet: aluminum hydroxide/ magnesium trisilicate) Brand product is discontinued but generic equivalents are available Over-the-counter product	Look	Liquid: 95 mg/358 mg per 15 mL	Adult: 15 to 30 mL by mouth up to four times per day Pediatric: 5 to 15 mL by mouth up to four times per day	Dose: 1 effervescent tablet or 70 mg vs. 5 to 30 mL Frequency: once weekly vs. up to 4 times per day Dosage Form: effervescent tablet vs. liquid Other: Genaton was marketed in two different dosage formulations: liquid and chewable tablet. Thus, the dosage formulation or an adequate dose is needed to for dispensing (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
		Tablet, chewable: 80 mg/ 20 mg	2 to 4 tablets by mouth up to 4 times per day	Dose: 1 effervescent tablet or 70 mg vs. 2 to 4 tablets Frequency: once weekly vs. up to 4 times per day Other: Same as above
Kemstro (baclofen) Brand orally disintegrating tablet is discontinued but generic baclofen tablets are available	Look	Orally disintegrating tablet: 10 mg and 20 mg (Baclofen tablets are also available in 10 mg and 20 mg)	Initiate doses at 5 mg placed on tongue three times a day for 3 days, 10 mg three times a day for 3 days, 15 mg three times a day for 3 days, and 20 mg three times a day for 3 days. Maximum dose is 80 mg per day	Strength: single strength (70 mg) vs. multiple strengths (10 mg and 20 mg) Frequency: once weekly vs. three times a day
Lunesta (eszopiclone)	Look	Tablet: 1 mg, 2 mg and 3 mg	1 to 3 mg by mouth immediately before bedtime	Strength: single strength (70 mg) vs. multiple strengths (1 mg, 2 mg and 3 mg) Frequency: once weekly vs. immediately before bedtime
Menest (estrogens, esterified)	Look	Tablet: 0.3 mg, 0.625 mg, 1.25 mg and 2.5 mg	Vasomotor symptoms: 1.25 mg by mouth once daily for 3 weeks on and 1 week off Moderate to severe symptoms of vulvar and vaginal atrophy: 0.3 mg to 1.25 mg or more by mouth once daily for 3 weeks on and 1 week off Female hypogonadism: 2.5 mg to 7.5 mg by mouth in divided doses for 20 days followed by a 10-day	Strength: single strength (70 mg) vs. multiple strengths (0.3 mg, 0.625 mg, 1.25 mg and 2.5 mg) Frequency: once weekly vs. once daily or in divided doses per day

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
			rest period. Female castration and primary ovarian failure: 1.25 mg by mouth once daily for 3 weeks on and 1 week off.	
Menostar (estradiol)	Look	Patch, transdermal: 0.014 mg/24 hours	Osteoporosis prevention: apply 1 patch topically once weekly.	Dose: 1 effervescent tablet or 70 mg vs. 1 patch Route of administration: oral vs. topical Dosage Form: effervescent tablet vs. transdermal patch
Minocin Minocin PAC (minocycline)	Look	Capsule: 50 mg and 100 mg	50 mg to 200 mg by mouth every 12 hours	Frequency: once weekly vs. every 12 hours Other: Minocin 100 mg is marketed in two different dosage formulations: capsule and injection. Thus, the dosage formulation must be indicated on the prescription (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.
		Injection, powder for reconstitution: 100 mg	200 mg initially, followed by 100 mg intravenous injection every 12 hours	Dose: 1 effervescent tablet or 70 mg vs. 100 mg or 200 mg Frequency: once weekly vs. every 12 hours Dosage Form: effervescent tablet vs. injection Other: same as above
Prezista (darunavir)	Look	Tablet: 75 mg, 150 mg, 400 mg and 600 mg	Therapy-naïve: 800 mg (two 400 mg tablets) by mouth once daily Therapy-experienced:	Strength: single strength (70 mg) vs. multiple strengths (75 mg, 150 mg, 400 mg and 600 mg) Frequency: once weekly vs. once or twice daily

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
			800 mg by mouth once daily with no resistance-associated substitutions, or 600 mg by mouth twice daily with 1 or more resistance-associated substitution or if no genotype testing.	Orthographic Differences: Prezista contains a down stroke letter "z" when scripted in cursive, which is not seen in Binosto.
Renvela (sevelamer carbonate)	Look	Powder for suspension, oral: 0.8 g/packet and 2.4 g/packet	Patients not taking a phosphate binder: 0.8 g to 1.6 g by mouth three times daily with meals Patient switching from calcium acetate to Renvela: 0.8 g to 2.4 g by mouth three times daily with meals Dose Titration for all patients taking Renvela: titrate dose by 0.8 g three times per day with meals at two-week intervals as necessary with goal of controlling serum phosphorus within target range: average daily dose is 7.2 g per day based on clinical studies.	Strength: single strength (70 mg) vs. multiple strengths (0.8 g/packet and 2.4 g/packet) Dose: 1 effervescent tablet or 70 mg vs. # mg or # packet Frequency: once weekly vs. three times daily Orthographic Differences: Binosto contains a dotted letter "i" and a cross-stroke letter "t", both of which are not seen in Renvela. Other: Renvela is marketed in two different dosage formulations: oral suspension and tablet. Thus, either the strength or dosage formulation must be indicated on the prescription (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.
		Tablet: 800 mg	Same as above	Frequency: once weekly vs. three times daily Orthographic Differences: same as above Other: same as above

Product name with potential for confusion	Similarity to Binosto	Dosage Form/ Strength	Usual Dose (if applicable)	Name confusion is prevented by the stated product characteristics and/or orthographic/phonetic differences as described
Binosto (alendronate sodium)	n/a	Effervescent tablet: 70 mg	Dissolve 1 effervescent tablet in half a glass of water, stir for 10 seconds, then drink dissolved contents by mouth once weekly #4 or 12	n/a
Revatio (sildenafil)	Look	Injection, solution: 0.8 mg/mL	10 mg intravenous infusion three times daily	Dose: 1 effervescent tablet or 70 mg vs. 10 mg or 125 mL Frequency: once weekly vs. three times daily Dosage Form: effervescent tablet vs. injection Other: Revatio is marketed in two different dosage formulations: oral suspension and tablet. Thus, either the strength or dosage formulation must be indicated on the prescription (which would then provide differentiating product characteristics from Binosto); or the dispenser would have to contact the prescriber for verification.
		Tablet: 20 mg	20 mg by mouth three times daily, taken four to six hours apart	Frequency: once weekly vs. three times daily Other: same as above
Revonto (dantrolene)	Look	Injection, powder for reconstitution: 20 mg	Malignant hyperthermia, preoperative prophylaxis: 2.5 mg/kg intravenous infusion ~$1^1/_4$ hours prior to anesthesia and infused over 1 hour with additional doses as needed and individualized Malignant hyperthermia, crisis: 2.5 mg/kg intravenous infusion, continuously repeat dose until symptoms subside or a cumulative dose of 10 mg/kg is reached	Dose: 1 effervescent tablet or 70 mg vs. 180 mg (based on the 72 kg average adult weight) Frequency: once weekly vs. prior to anesthesia or during malignant hyperthermia crisis Dosage Form: effervescent tablet vs. injection Orthographic Differences: Binosto contains a dotted letter "i" that is not seen in Revonto. Other: Binosto is prescribed for outpatient use vs. Revonto is ordered in inpatient hospital settings such as the operation room

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09/07/2011

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09/08/2011

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09/09/2011

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:	May 2, 2011
Application Type/Number:	IND 103130 NDA 202344
Through:	Carlos M Mena-Grillasca, RPh, Team Leader Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis
From:	Chi-Ming Tu, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s)/ Strength:	Steovess (Alendronate) Effervescent Tablets, 70 mg
Applicant	EffRx Pharmaceuticals SA
OSE RCM #:	2010-2601

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