

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203341Orig1s000

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: July 26, 2012

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

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

Drug Name and Strengths: Bosulif (Bosutinib) Tablets,
100 mg and 500 mg

Application Type/Number: NDA 203341

Applicant/sponsor: Wyeth Pharmaceutical, Inc.

OSE RCM #: 2012-1138

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Bosulif, 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, Bosulif, acceptable in OSE Review #2010-381, dated July 13, 2010, under IND 068268 and OSE Review #2011-4348, dated February 3, 2012.

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 2011-4348.

We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which did not alter our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases yielded three new names (Duricef, Foradil, and Roxilox), thought to look similar to Bosulif 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 Duricef, Foradil, and Roxilox and lead to medication errors. This analysis determined that the name similarity between Bosulif and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

Additionally, DMEPA searched the United States Adopted Names (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 USAN stems in the proposed proprietary name, as of July 23, 2012. The Office of Prescription Drug Promotion OPDP re-reviewed the proposed name on June 14, 2012 and had no concerns regarding the proposed name from a promotional perspective.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Bosulif, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Bosulif, 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 Hematology Products 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 Sue Kang, OSE project manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

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

4. REFERENCES

1. **OSE Reviews 2011-4348 Bosulif (Bosutinib) Tablets, 100 mg and 500 mg, Kimberly DeFronzo, RPh, MS, MBA, February 3, 2012.**
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

<p>Proposed Name: Bosulif (bosutinib) Strength and Dosage Form: 100 mg, 500 mg oral tablets Usual Dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Duricef (cefadroxil) - 500 mg oral capsules - 1 gram oral tablets - 250 mg/5 mL oral suspension (50, 100 mL) - 500 mg/5 mL oral suspension (75, 100 mL) - 1 to 2 grams/day in a single or divided doses (twice daily) - Pediatrics: 30 mg/kg/day in divided doses every 12 hours - Renal impairment: initial dose 1 gram then 500 mg every 12 to 36 hours</p>	<p>Orthographic Similarities - ‘Bos’ and ‘Dur’ may appear similar when scripted - ‘if’ and ‘ef’ may appear similar when scripted - Both have 7 letters Overlapping Product Characteristics - Strength (500 mg, 500 mg/5 mL) - Dosage Form (tablets/capsules)</p>	<p>Orthographic Differences - 3 up strokes vs. 2 up strokes - ‘ul’ and ‘ic’ appear different when scripted</p>
<p>Foradil (formoterol) - 0.012 mg powder in capsules for inhalation - Inhale 1 capsule every 12 hours</p>	<p>Orthographic Similarities - ‘Bos’ and ‘For’ may appear similar when scripted - ‘if’ and ‘il’ may appear similar when scripted - Both have 7 letters Overlapping Product Characteristics - Dosage Form (tablets/capsule)</p>	<p>Orthographic Differences - ‘ul’ and ‘ad’ appear different when scripted Differing Product Characteristics - Strength (100 mg, 500 mg vs. 0.012 mg single strength)</p>

<p>Proposed Name: Bosulif (bosutinib) Strength and Dosage Form: 100 mg, 500 mg oral tablets Usual Dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)</p>	<p>Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
<p>Roxilox (acetaminophen/oxycodone) - 500 mg/5 mg oral capsules - 1 capsule every 6 hours as needed</p>	<p>Orthographic Similarities - ‘Bosul’ and ‘Roxil’ may appear similar when scripted - Both have 7 letters</p> <p>Overlapping Product Characteristics - Dosage Form (tablets/capsule) - Strength (500 mg, 500 mg/5 mg)</p>	<p>Orthographic Differences - ‘if’ and ‘ox’ appear different when scripted - 3 up strokes vs. 2 up strokes</p> <p>Differing Product Characteristics - Frequency of Administration (once daily vs. every 6 hours as needed)</p>

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/s/

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**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: February 3, 2012

Reviewer: Kimberly DeFronzo, RPh, MS, MBA
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: Bosulif (Bosutinib) Tablets
100 mg and 500 mg

Application Type/Number: NDA 203341

Applicant: Pfizer, Inc. (Wyeth Pharmaceutical, Inc.
is a wholly-owned subsidiary of Pfizer, Inc.)

OSE RCM #: 2011-4348

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Bosulif, 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 HISTORY

The proposed proprietary name, Bosulif, was found acceptable by DMEPA in OSE Review #2010-381, dated July 13, 2010, under IND 068268. At the August 18, 2010 PreNDA meeting, DMEPA did not identify any safety concern during the review of the meeting package. The Applicant submitted a proprietary name request on November 17, 2011 under NDA 203341 for the same name which is the topic of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 17, 2011 proprietary name submission.

- Active ingredient: Bosutinib
- Indication of Use: for the treatment of chronic, accelerated, or blast phase Ph+ chronic myelogenous leukemia (CML) in adult patients with resistance, or intolerance to prior therapy.
- Route of administration: Oral
- Dosage form: Tablets
- Dose and Frequency: 500 mg once daily with food. Dose escalation to 600 mg once daily with food in patients who failed to reach complete hematological response (CHR) by week 8 or a complete cytogenetic response (CCyR) by week 12, at the recommended starting dosage and who did not have Grade 3 or higher adverse reactions. Dose adjustment for non-hematologic toxicities such as elevated liver transaminases and diarrhea, include drug interruption and resuming at a dose of 400 mg once daily. Dose adjustment for hematologic toxicities such as neutropenia and thrombocytopenia, include drug interruption and resuming at a dose reduction by 100 mg once daily. A lower starting dose of 200 mg is recommended in patients with hepatic impairment. No dose adjustment is recommended in patients with renal impairment or the elderly, and no data is available in patients less than 18 years of age.
- How Supplied:
 - 120 tablets per bottle of 100 mg tablets (NDC #0069-0135-01) that are yellow, oval, biconvex, film-coated tablets, debossed "Pfizer" on one side and "100" on the other
 - 30 tablets per bottle of 500 mg tablets (NDC #0069-0136-01) that are red, oval, biconvex, film-coated tablets, debossed "Pfizer" on one side and "500" on the other

- Storage: at 25°C (77 °F); excursions permitted to 15- 30°C (59-86°F) [see USP Controlled Room Temperature].
- Container and Closure Systems: The commercial container closure system for Bosutinib 100 mg and 500 mg tablets consists of a high-density polyethylene bottle/closure system with desiccant as outlined in the table below.

HDPE Bottle/Closure System				
Strength	Count	Bottle Size (mL)	Closure Size (mm)	Desiccant Canister
100 mg	120	60	28	1 per bottle
500 mg	30	60	28	1 per bottle

Additionally, the insert labeling suggests the following:

- Procedures for proper disposal of anticancer drugs should be considered. Any unused product or waste material should be disposed of in accordance with local requirements, or drug take back programs.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP’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

On December 1, 2011 the 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

This proprietary name comprised of a single word that does not contain any components such as a modifier, route of administration, or dosage form that is misleading or can contribute to medication error. The Applicant notes in their submission that the proprietary name is an invented name with no meaning and is derived from the prefix of the established name.

2.2.3 FDA Name Simulation Studies

Thirty-nine practitioners participated in DMEPA’s prescription studies. Two interpretations cited the name “Bacillus” which is a genus of bacteria and therefore, will not be further evaluated. The most common misinterpretation in the written studies was

the lowercase letter ‘u’ for the lowercase letter ‘a’ and lowercase letter ‘b’ for lowercase letter ‘l’. The most common misinterpretation in the verbal study was the sound from letter ‘B’ for the letters ‘O’ and ‘P’. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines

In response to the OSE’s December 2, 2011 e-mail, DHP did not forward any comments or issues relating to the proposed name at the initial phase of the proprietary name review.

2.2.6 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Bosulif. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Bosulif, identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified from the FDA Prescription Simulation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, FDA Name Simulation Studies, and External Name Study if applicable)

Look Similar		Look Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
(b) (4)	FDA	Bismuth	FDA	Bosulif***	FDA
Basulin	FDA	Lescol XL	FDA	Bosutinib	FDA
Paralit	FDA	Bontril	FDA	Busulfex	FDA
Borobag	FDA	Velosef	FDA	Fusilev	FDA
Biscolax	FDA	Bionect	FDA	Busulfan	FDA
Beelith	FDA	Dexilant	FDA	Rosula	FDA
Bosentan	FDA	Baclofen	FDA		
Bisacodyl	FDA	Rosanil	FDA		
Disulfiram	FDA	Roxilox	FDA	Sound Similar	
Banzel	FDA	Derifil	FDA	<i>Name</i>	<i>Source</i>
Brevital Sodium	FDA	Buspar	FDA	Dosaflex	FDA
Diastat	FDA				

Our analysis of the 30 names contained in above Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined these 30 names will not pose a risk for confusion as described in Appendix E through F.

2.2.7 Communication of DMEPA's Final Decision to Other Disciplines

DMEPA communicated our findings to the DHP via e-mail on January 23, 2012. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DHP on January 25, 2012, they stated no issues with the proposed proprietary name, Bosulif.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective. If you have further questions or need clarifications, please contact Sue Kang, OSE Project Manager, at 301-796-4216.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Bosulif, and have concluded that this name is acceptable. This proprietary name must be re-evaluated 90 days prior to the approval of the application. The conclusions upon re-review are subject to change.

However, if any of the proposed product characteristics as stated in your November 17, 2011 submission are altered, DMEPA rescinds this finding and the name must be resubmitted for review.

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. This database also lists the orphan drugs.

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. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. ***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.

9. 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.

10. 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.

11. 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.

12. 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.

13. Red Book Pharmacy's Fundamental Reference

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

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

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

15. Medical Abbreviations Book

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

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. OSE Reviews

Pincock, Laura L. OSE Review 2010-381: Proprietary Name Review for Bosulif, July 13, 2010.

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 OPDP. OPDP 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. OPDP 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

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).

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

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		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> 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/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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 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 (OPDP). 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 OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

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

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

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

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

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 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 possess 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. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’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

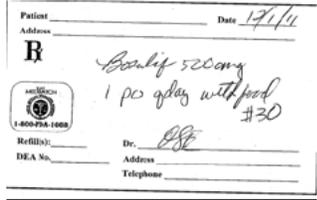
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval 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, Bosulif	Scripted May Appear as	Spoken May Be Interpreted as
Capital ‘B’	H, R, P, D, L, V, E, F, O, C, I	P, D, V, O
Lower case ‘b’	h, l, li	P, D, V
lowercase ‘o’	a, c, e, u	Oh
lowercase ‘s’	n, r, z	x, z
lowercase ‘u’	n, y, v, w, m, r	any vowel
lowercase ‘l’	b, e, s, r, i	---
lowercase ‘i’	e, l, r	any vowel
lowercase ‘f’;	t, l	---

Appendix C: Prescription Simulation Samples and Results

Figure 1. Bosulif Study (Conducted on December 6, 2011)

Handwritten Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> <p><i>Bosulif 500mg po qday with breakfast</i></p>	<p>“Bosulif 500 mg Directions for use: take one by mouth daily with food Disp#30”</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses

As of Date 1/13/2012

85 People Received Study

39 People Responded

Study Name: Bosulif

INPATIENT	VOICE	OUTPATIENT
BOSUBIF (4)	BACILLUS (2)	BOSALIF (2)
BOSULIF (7)	BOCILIS (1)	BOSULIF (14)
	BOSILIS (2)	
	BOSULESS (1)	
	BOSULIF (1)	
	BRACILIS (1)	
	BUSILLUSS (1)	
	OSCILLAS (1)	
	POSCILLUS (1)	
	POSSILUS (1)	

Appendix D: Proprietary names determined in OSE Review 2010-381 not likely to lead to a medication error.

Proprietary Name	Active Ingredient	Similarity to Bosulif
(b) (4)		
Bensufoid	Sulfur	Look
Bosentan	Established name for Tracleer	Look
Focalin	Dexmethylphenidate	Look
Rindal	Chlorpheniramine, Hydrocodone, and Phenylephrine	Look
Onsolis	Fentanyl	Look
Baclofen	Established name for Lioresal and Gablofen	Look
Curosurf	Poractant alfa	Look
Infasurf	Calfactant	Look
Rosula	Sodium Sulfacetamide and Sulfur	Look
Bisa-Lax	Bisacodyl	Look
Elestat	Epinastine HCl	Look
Vosol HC	Acetic acid and Hydrocortisone	Look
Bontril	Phendimetrazine tartrate	Look
Busulfan	Established name for Busulfex	Look
Busulfex	Busulfan	Look

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

Proprietary Name	Active Ingredient	Similarity to Bosulif
Bosulin	Powder of silkworms	Sound
Fusilev	Levoleucovorin	Look & Sound
(b) (4)		

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

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

Proprietary Name	Active Ingredient	Similarity to Bosulif	Failure preventions
Bisco-Lax	Bisacodyl	Look	Lacks significant orthographic similarities
Bisacodyl	Bisacodyl	Look	Lacks significant orthographic similarities
Basulin	not known	Look	Trademarked name by Flamel Technologies that specializes in drug delivery systems. Basulin name was not found on the company website. Product characteristics not found in commonly used drug databases (e.g., Redbook, Clinical Pharmacology, Facts & Comparisons online, Drugs@FDA, and Micromedex).
Paralit	not known	Look	Trademarked name by Angstrom Pharmaceuticals but no information can be found on the company website. Product characteristics not found in commonly used drug databases (e.g., Redbook, Clinical Pharmacology, Facts & Comparisons online, Drugs@FDA, and Micromedex).
Borobag	not known	Look	Product characteristics not found in commonly used drug databases (e.g., Redbook, Clinical Pharmacology, Facts & Comparisons online, Drugs@FDA, and Micromedex).
Disulfiram	Established name for Antabuse	Look	Lacks significant orthographic similarities
Diastat	Diazepam	Look	Lacks significant orthographic similarities
Lescol XL	Fluvastatin	Look	Lacks significant orthographic similarities
Velosef	Cephadrine	Look	Lacks significant orthographic similarities
Dexilant	Dexlansoprazole	Look	Lacks significant orthographic similarities

Proprietary Name	Active Ingredient	Similarity to Bosulif	Failure preventions
Rosanil	Sulfacetamide sodium	Look	Lacks significant orthographic similarities
Roxilox	Oxycodone HCl	Look	Lacks significant orthographic similarities
Derifil	Chlorophyllin copper complex sodium	Look	Lacks significant orthographic similarities
Dosaflex	Senna pod obtained from Cassia Senna	Sound	Lacks significant phonetic similarities
Bosulif***	Bosutinib	Look & Sound	Trademarked by Wyeth, LLC which is the Applicant for this NDA
Bosutinib	Bosutinib	Look & Sound	Established name for proposed tradename Bosulif
(b) (4)			
Bosetan	Established name for Tracleer	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error
Bontril	Phendimetrazine tartrate	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error
Busulfex	Busulfan	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error
Busulfan	Established name for Busulfex	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error
Rosula	Sodium Sulfacetamide and Sulfur	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error

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

Proprietary Name	Active Ingredient	Similarity to Bosulif	Failure preventions
Baclofen	Established name for Lioresal and Gablofen	Look	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error
Fusilev	Levoleucovorin	Look & Sound	Previously assessed in OSE Review #2010-381 and determined not likely to lead to a medication error

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

<p>Proposed name: Bosulif (Bosutinib) Tablets</p>	<p>Strength(s): 100 mg and 500 mg Tablets</p>	<p>Usual dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)</p>
<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p>	<p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p>
<p>Beelith (Magnesium Oxide, Pyridoxine) 362 mg/25 mg Tablet Usual Dose: Take one tablet daily with food or as directed by physician (This is an OTC vitamin)</p>	<p>Orthographic similarity - Both names begin with the letter ‘B’ followed by a vowel ‘o’ and ‘e’ that look similar when scripted - Both names share upstroke letters (‘l’, ‘f’ vs. ‘l’, ‘th’) -Both name have dotted letter (‘i’) near ending of the names -Both names are identical in length with 7 letters Product characteristic similarity - Same dose (one tablet), same frequency (once daily), same dosage form (tablet), route of administration (orally), same directions for use (take with food), same storage condition (room temperature)</p>	<p>Orthographic differences - Beelith contains an additional upstroke letter ‘h’ Product characteristic differences - Different strengths (since the strength must be specified on a prescription for Bosulif, this provides an opportunity for product clarification)</p>
<p>Banzel (Rufinamide) 200 mg, 400 mg tablets 40 mg/mL oral suspension Usual Dose: 400-800 mg/day given in 2 divided doses</p>	<p>Orthographic similarity -Both names begin with the letter ‘B’ followed by a vowel ‘o’ and ‘a’ that look similar when scripted -Both names share same ending upstroke letters (‘f’ vs. ‘l’) that look similar when scripted -Both names are similar in length</p>	<p>Orthographic differences - Bosulif contains an additional upstroke letter ‘l’ and the dotted letter ‘i’ Product characteristic differences - Different strengths (100 mg and 500 mg vs. 200 mg and 400 mg)</p>

Proposed name: Bosulif (Bosutinib) Tablets	Strength(s): 100 mg and 500 mg Tablets	Usual dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
	with 7 vs. 6 letters Product characteristic similarity - Same dose (one tablet), same dosage form (tablet), route of administration (orally), same storage condition (room temperature)	- Directions for use (daily with food vs. two divided doses)
Brevital (Methohexital) 500 mg, 2.5 gm, 5 gm Powder for Injection Usual Dose: 1-1.5 mg/kg IV of a 1% solution given at a rate of about 1 ml per 5 seconds (ranging from 50mg to 120 mg) for induction	Orthographic similarity -Both names begin with the letter 'B' followed by 'o' and 'r' that look similar when scripted -Both names share same ending upstroke letters ('f' vs. 'l') that look similar when scripted -Both names are similar in length with 7 vs. 8 letters -Both name have dotted letter ('i') - Both name share same number of upstroke letters in same positions Numeric similarity - Overlapping strength (500 mg)	Orthographic differences - Brevital contains a crosstroke letter 't' Product characteristic differences - Different dose (200 mg to 600 mg for Bosulif vs. must be calculated for Brevital) - Different dosage form (tablet vs. powder for injection that must be reconstituted prior to administration) - Different route of administration (oral vs. intravenous) - Different directions for use (daily with food vs. one time dosing for induction purposes)
Bionect (Hyaluronate Sodium) 0.2% Topical	Orthographic similarity - Both names begin with the letter 'B' followed by a vowel 'o' and 'i' that look similar when scripted	Orthographic differences - Bionect lacks the second upstroke letter 'l' -The position of the dotted letter 'i'

Proposed name: Bosulif (Bosutinib) Tablets	Strength(s): 100 mg and 500 mg Tablets	Usual dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
Gel, Cream, Spray Usual Dose: Apply to affected area three times daily	<ul style="list-style-type: none"> - Both names share upstroke ending letters ('f' and 't') -Both name have dotted letter ('i') -Both names are identical in length with 7 letters Product characteristic similarity <ul style="list-style-type: none"> -Same storage condition (room temperature) 	is in different positions (at end vs. beginning of the name) Product characteristic differences <ul style="list-style-type: none"> - Different strengths (since the strength must be specified on a prescription for Bosulif, this provides an opportunity for product clarification) -Different dosing instruction (take one tablet vs. apply) -Different frequency of administration (once daily vs. three times daily)
Bismuth (Bismuth Subsalicylate) 262 mg Chewable Tablet, 262 mg Oral Tablet, 262 mg/15mL Oral Suspension, 525 mg/15 mL Oral Suspension, 527 mg/30 mL Oral Suspension, 87 mg/5 mL Oral Suspension Usual Dose: 524 mg (2 tablets) orally every 30-60 minutes as needed or 524 mg (30 ml of the 262 mg/15 mL strength) orally every 30-60 minutes	Orthographic similarity <ul style="list-style-type: none"> - Both names begin with the letters 'B-s' with the middle vowels 'o' and 'i' that look similar when scripted - Both names share same 3 upstrokes letters -Both name have dotted letter ('i') -Both names are identical in length with 7 letters Product characteristic similarity <ul style="list-style-type: none"> -Same dosage form (tablet) -Same route of administration (oral) 	Orthographic differences <ul style="list-style-type: none"> -There is a letter in between the two ending upstrokes in Bosulif that is not present in Bismuth Product characteristic differences <ul style="list-style-type: none"> - Different strengths (since the strength must be specified on a prescription for Bosulif, this provides an opportunity for product clarification) -Different frequency of administration (once daily vs. 30-60 mins as needed)

Proposed name: Bosulif (Bosutinib) Tablets	Strength(s): 100 mg and 500 mg Tablets	Usual dose: 200 mg to 600 mg orally once daily with food (including dose adjustment)
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
as needed (This is an OTC monograph product)	-Same potential dose (if written by number of tablets to be taken) -Same storage condition (room temperature)	
Buspar (Buspirone Hydrochloride) 5 mg and 10 mg Tablets 15 mg and 30 mg Dividose Tablets Usual Dose: Initially 15 mg daily (or 7.5 mg bid) then increase as needed by 5 mg/day every 2-3 days. Maintenance dose is 15 mg to 30 mg daily administered in 2-3 divided doses	Orthographic similarity - Both names begin with the letters 'B-s' with the middle vowels 'o' and 'u' that look similar when scripted -Both names are similar in length with 7 vs. 6 letters Product characteristic similarity - Same dosage form (tablet), route of administration (orally), same storage condition (room temperature) -Numerical overlapping strength with 100 mg Bosulif and 10 mg Buspar -Same potential dose (if written by number of tablets to be taken)	Orthographic differences - Bosulif contains two upstroke letters 'l' and 'f' that are lacking in Buspar -Buspar contains a downstroke letter 'p' that is lacking in Bosulif Product characteristic differences - Different dose (7.5 mg to 30 mg vs. 200 mg to 600 mg daily doses)

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/s/

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