CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022433Orig1s000

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

Date:	December 1, 2010
Application Type/Number:	NDA 022433
Through:	Irene Z. Chan, Pharm.D, BCPS, Acting Team Leader Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Charlene A. Baksh, Pharm.D, Ph.D, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Brilinta (Ticagrelor) Tablets 90 mg
Applicant:	AstraZeneca LP
OSE RCM #:	2010-2010

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proprietary name responds to a notification that NDA 022433 may be approved within 90 days. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Brilinta, acceptable in OSE Review #2009-2287, dated February 16, 2010, and OSE Review #2010-645 dated July 2, 2010.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-2287 for the proposed proprietary name, Brilinta. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates.

The searches of the databases yielded no new names thought to look similar to Brilinta and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Brilinta, as of November 15, 2010.

3 CONCLUSIONS AND RECOMMENDATIONS

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

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

4 REFERENCES

1. **OSE review #2009-2287 Proprietary Name Review of Brilinta; Toombs, L. Shenee'.**
2. **OSE review #2010-645 Proprietary Name Review of Brilinta; Toombs, L. Shenee'.**
3. ***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.
4. ***USAN Stems (***http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml***)***
   USAN Stems List contains all the recognized USAN stems.
5. ***Division of Medication Error Prevention and Analysis proprietary name requests***
   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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

/s/

CHARLENE A BAKSH
12/01/2010

IRENE Z CHAN
12/01/2010

CAROL A HOLQUIST
12/02/2010

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	February 16, 2010
To:	Norman Stockbridge, MD, Director Division of Cardiovascular and Renal Products
Thru:	Carlos Mena-Grillasca, RPh, Team Leader Denise Toyer, PharmD, Deputy Director Carol Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	L. Shenee' Toombs, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Brilinta (Ticagrelor) Tablets 90 mg
Application Type/Number:	NDA 022433
Sponsor:	AstraZeneca LP
OSE RCM #:	2009-2287

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

****This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through FDA/CDER Office of Surveillance and Epidemiology.****

CONTENTS

EXECUTIVE SUMMARY

Brilinta is the proposed proprietary name for Ticagrelor Tablets. This proposed name was evaluated from a safety and promotional perspective based on the product characteristics provided by the Applicant. We sought input from pertinent disciplines involved with the review of this application and considered it accordingly. Our evaluation did not identify concerns that would render the name unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, DMEPA finds the proposed proprietary name, Brilinta, acceptable for this product.

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

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

1 BACKGROUND

1.1 INTRODUCTION

This review is written in response to a request from AstraZeneca, dated November 20, 2009 to evaluate the proposed proprietary name, Brilinta, regarding potential name confusion with other proprietary or established drug names in the usual practice setting. Additionally, the Applicant submitted container labels and carton labeling for review, which will be reviewed under separate cover (OSE Review #2009-2288).

1.2 PRODUCT INFORMATION

Brilinta is indicated to reduce the rate of thrombotic events (including stent thrombosis) for patients with ACS (unstable angina, non ST elevation myocardial infarction or ST elevation myocardial infarction) who are to be managed medically or are to be managed invasively with percutaneous coronary intervention (with or without stent) and/or CABG.

The recommended dose is 180 mg orally once, followed by 90 mg orally twice daily. Brilinta will be available in 90 mg tablets and packaged in bottles of 8, 60, and 180 tablets and 100 count hospital unit dose blisters. It should be stored at 25˚C (77˚F).

1.3 REGULATORY HISTORY

DMEPA previously reviewed this proposed proprietary name, Brilinta, under IND 065808 (OSE Review #2009-417 dated August 13, 2009). We found the name conditionally acceptable at that time.

2 METHODS AND MATERIALS

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

2.1 SEARCH CRITERIA

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

---

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

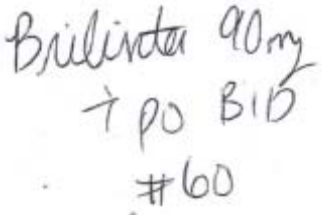
To identify drug names that may look similar to 'Brilinta', the DMEPA staff also considers the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (eight letters), upstrokes (3, capital letter 'B', lower case 'l', and lowercase't'), downstrokes (none), and crosstrokes (one, lowercase letter 't'). Additionally, several letters in Brilinta may be vulnerable to ambiguity when scripted including the letter 'B' which may appear as uppercase 'D','K', 'R', 'M', or 'Pr'; lowercase 'r' appear as a lowercase 'n', 's', 't' or 'v'; lowercase 'i' appear as a lowercase 'c', 'e' or 'l' when undotted; lowercase 'l' appear as lowercase 'e', undotted 'i' or uncrossed t'; lowercase 'n' appear as lowercase 'h', 'm', 'r', 's', or 'v'; lowercase 't' appear as lowercase 'f', 'l' (if 't' is uncrossed), or 'r'; and lowercase 'a' appear as lowercase 'c', 'ce', 'ci', 'cl', 'e', 'o', or 'u'. As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Brilinta.

When searching to identify potential names that may sound similar to Brilinta, the DMEPA staff searches for names with similar number of syllables (three), stresses (BRI-lin-ta, bri-LIN-ta, or bri-lin-TA), and placement of vowel and consonant sounds. Additionally, the DMEPA staff considers that pronunciation of parts of the name can vary, such as the letters "Bril" which may be interpreted as "Brill", "Brul", or "Brel"; "lin" which may be interpreted as "len"; and "ta" which may be interpreted as "tah" or "da". The Sponsor provided their intended pronunciation of the proprietary name (brih-LIN-tah) in the proposed name submission and, therefore, it was taken into consideration. However, names are often mispronounced and/or spoken with regional accents and dialects, so other potential pronunciations of the name are considered.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

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

Figure 1. Brilinta Study (conducted on December 04, 2009)

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Inpatient Medication Order: 	Brilinta 90 mg i po BID #60
Outpatient Prescription: 	

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

2.3 EXTERNAL PROPRIETARY NAME RISK ASSESSMENT

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

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

3 RESULTS

3.1 DATABASE AND INFORMATION SOURCES

The searches yielded a total of 18 names as having some similarity to the name Brilinta.

Seventeen of the 18 names (Dilantin, Relenza, Brevital, Prinivil, Prinzide, Rilutek, Prialt, Ritalin LA, Bontril, Sulindac, Phrenilin, Prilosec, Sufenta, Betadine, Mylanta, Ritalin, Zileuton) were thought to look like Brilinta. One name, Brilliant Green, was thought to look and sound similar to Brilinta.

A search of the United States Adopted Name stem list on December 13, 2009 did not identify any United States Adopted Names (USAN) stem within the proposed name, Brilinta.

3.2 EXPERT PANEL DISCUSSION

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

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total of 15 practitioners responded. Nine (n=9) respondents interpreted the name correctly as 'Brilinta', with correct interpretations occurring in both inpatient (n=5) and outpatient (n=4) written studies. The remainder of the written study responses misinterpreted the drug name, with the most common misinterpretation occurring in the last syllable of the name. ('ter' vs 'ta'). In the verbal studies responses were misspelled phonetic variations of the proposed name, Brilinta, with the most common variation occurring in the first syllable of the name ('Bur' or 'Ber' vs 'Bri').

3.4 EXTERNAL NAME STUDY

The proposed name risk assessment submitted by the Applicant, (b) (4) found the proposed name acceptable. They identified and evaluated a total of 32 drug names thought to have some potential for confusion with the name Brilinta (see Appendix C).

Of those 32 names, DMEPA identified the following 4 names in their searches: Dilantin, Mylanta, Relenza and Sufenta. The remaining 28 names will be evaluated in the Safety Evaluator Risk Assessment.

3.5 COMMENTS FROM THE DIVISION OF CARDIOVASCULAR AND RENAL PRODUCTS (DCRP)

3.5.1 Initial Phase of Review

In response to the OSE December 03, 2009 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not object to the proposed proprietary name Brilinta.

3.5.2 Midpoint of Review

On January 08, 2010 DMEPA notified the Division of Cardiovascular and Renal Products (DCRP) via e-mail that we had no objections to the proposed proprietary name Brilinta. Per e-mail correspondence from DCRP on January 13, 2010 they indicated they concur with our assessment of the proposed proprietary name, Brilinta

3.6 SAFETY EVALUATOR RISK ASSESSMENT

Independent searches by the primary Safety Evaluator identified three additional names, Balanta, (b) (4)*** and (b) (4)*** thought to look or sound similar and represent a potential source of confusion to Brilinta. Thus, we identified and evaluated a total of forty-nine names for their similarity to the proposed name (eighteen from the Expert Panel Discussion, twenty-eight from the Independent Study, and three identified by the Safety Evaluator).

4 DISCUSSION

4.1 PROMOTIONAL REVIEW

DDMAC did not find the name Brilinta promotional. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) concurred with this assessment.

4.2 SAFETY REVIEW

DMEPA sought input from all stakeholders (Clinical, CMC, DDMAC) on the safety aspects of the name. No issues were identified from these stakeholders. DMEPA identified and evaluated a total of forty-nine names for their potential similarity to the proposed name, Brilinta. DMEPA did not identify any other aspects of the name as a potential source of confusion. Thirty-seven of the forty-nine names were previously reviewed in OSE review 2009-417 dated August 13, 2009. This includes all of the names identified by (b) (4) in Appendix C and the following five names: (b) (4)***, Brevital, Balanta, (b) (4)***, and Prialt. Since the product characteristics of Brilinta and these thirty-seven names have not changed since our previous review, these names were not re-reviewed. Of the remaining twelve names, eight names were determined to lack convincing orthographic and/or phonetic similarity to Brilinta, and therefore were not evaluated further (see Appendix D).

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

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

5 CONCLUSIONS AND RECOMMENDATIONS

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

However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. Furthermore, if the approval of this application is delayed beyond 90 days from the signature date of this review, the proposed name must be resubmitted for evaluation.

If you have further questions or need clarifications, please contact Nina Ton, OSE Project Manager at 301-796-1648.

5.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name, Brilinta, will be re-reviewed 90 days prior to the approval of the NDA. If we find the name unacceptable following the re-review, we will notify you.

If any of the proposed product characteristics are altered prior to approval of this NDA, the proprietary name should be resubmitted for review.

6 REFERENCES

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

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

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

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

Medical Abbreviations Book contains commonly used medical abbreviations and their definitions

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. 3

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

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

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

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

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

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

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

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

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

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

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

Lastly, the DMEPA staff also considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

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

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/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 the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

4. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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

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

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

---

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

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

a. DDMAC finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with DDMAC's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].
c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product.

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

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

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

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

Appendix B: FDA Prescription Study Responses

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
Brilinta	Brilinta	Burlinta
Brilinta	Brilinta	Berlinta or Berlanta
Brilinta	Brilinta	Relenta
Brilinta	Brilinter	
Brilinta	Brilinter	
	Brilinter	
	Brilinta	

Appendix C: Names identified in the (b) (4) Independent Name Analysis

Names	
Aricept	(b) (4)
Brethine	
Arixtra	
Boniva	
Buspar	
Dilantin	
Imitrex	
Senokot	
Sufenta	

Abilify	(b) (4)
Baclofen	
Beclovent	
Bicillin	
Bicitra	
Brevibloc	
Brimonidine	
Bumex	
Buspirone	
Butalbital	
Alimta	
Alfenta	
Plavix	
Verelan	
Mylanta	
Relenza	
Bretylium	
Insulin	
Byetta	
Lantus	
Amitiza	
Benicar	
Elimite	

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

Proprietary Name	Similarity to Brilinta
Bontril	Look
Phrenilin	Look
Prilosec	Look
Prinivil	Look
Prinzide	Look
Rilutek	Look
Ritalin LA	Look
Sulindac	Look

Appendix E: Products not likely to be written on a prescription

Proprietary Name	Similarity to Ereska	Reason
Brilliant Green	Look and Sound	Not identified as a drug. Antiseptic dye

Appendix F: Products with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Differentiating product characteristics
Brilinta **(Ticagrelor)** **Tablets**		**90 mg**	**180 mg orally once, followed by 90 mg orally twice daily**	
Betadine (Povidone-Iodine) Ophthalmic Solution	Look	5%	Prep solution for periocular region and irrigation of the ocular surface. Saturate sterile prep sponge to prep lids, brow and cheek in a circular ever-expanding fashion until the entire field is covered; repeat prep three times.	**Route of Administration:** Oral vs. Topical **Dosage Form:** Tablet vs Solution **Frequency of Administration:** twice daily vs. once **Dose:** 180 mg (2 tablets) once, then 90 mg (1 tablet) vs. "sufficient amount"

Appendix G: Proprietary names for single strength products with look and/or sound-alike similarities to Brilinta

Proposed name: **Brilinta (Ticagrelor) Tablets**	**Strength:** **90 mg**	**Usual dose: 180 mg orally once, followed by 90 mg orally twice daily.**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Rationale:**
Zileuton Tablets (Established name for the brand name products "Zyflo" and "Zyflo CR") Strength: Zyflo 600 mg Zyflo CR 600 mg Dose: 600 mg four times daily (Zyflo) 1200 mg twice daily (Zyflo CR)	Orthographic similarity ("B" vs. "Z") and ("-ilint" vs. "-ileut") Potential exists for the strength to be omitted on a prescription for either product	Medication errors unlikely to occur due to orthographic differences between the names in addition to differing doses. *Rationale*: The letter 'r' in Brilinta differentiates the names because it makes the beginning portion of the name appear longer than that of Zileuton ("Bri" vs. "Zi"). The ending letters ("a" vs. "n") have different shapes, which further helps to differentiate the names. *For Zileuton immediate-release tablets:* The products differ in dose and frequency (180 mg [2 tablets] once, then 90 mg [1 tablet] twice daily vs. 600 mg [1 tablet] four times daily). Although they overlap if "1 tablet" is written, Brilinta is prescribed for twice daily dosing versus four times daily for Zileuton. Outpatient retail pharmacy data** for calendar years 2007-2008 show that since the approval of Zyflo CR (May 30, 2007), prescriptions dispensed for Zyflo (immediate release) have (b) (4) Additionally, prescription drug usage data for calendar years 2004 through October 2009 as reported by office-based physicians were determined using (b) (4) and show that (b) (4) of Zyflo drug mentions (b) (4) were written with no product strength specified.[2] Since the approval of Zyflo CR, the use of Zyflo (b) (4) and only a small percentage of Zyflo prescriptions are written without the 600 mg strength indicated. This along with orthographic differences will minimize confusion. *For Zileuton extended-release tablets:* Zileuton is the established name and if it were prescribed using the established name, a prescriber would need to indicate if they wanted the extended-release formulation. (b) (4), Jan 2007-Oct 2009. Data Extracted Dec-2009. (b) (4), Jan 2004-Oct 2009 Extracted 12-2009.

** **This document contains proprietary drug use data obtained by FDA under contract. The drug use data/information cannot be released to the public/non-FDA personnel without contractor approval obtained through FDA/CDER Office of Surveillance and Epidemiology.****

Appendix H: Products with orthographic similarities but multiple differentiating characteristics.

Proposed name: **Brilinta (Ticagrelor) Tablets**	**Strength:** **90 mg**	**Usual dose: 180 mg orally once, followed by 90 mg orally twice daily.**
Failure Mode: Name confusion	**Causes (could be multiple)**	**Rationale:**
Ritalin (Methylphenidate) Tablets *Strengths:* 5 mg, 10 mg, 20 mg *Usual Dose:* 10 to 60 mg in 2 or 3 divided doses.	Orthographic similarity: ("B" vs. "R") Both names contain the letter string 'lin' Both names have a similar word shape Similar number of letters (8 letters vs 7 letters) Frequency of administration: (Twice daily vs. 2 or 3 times daily)	Medication errors unlikely to occur due to orthographic differences between the names and product strength and dosing differences. *Rationale:* Although both names contain the letter string 'lin', the positioning within the names is different. For Brilinta, the letter string 'lin' is in the second syllable and followed by the ending 'ta'. Conversely, for Ritalin the letter string 'lin' is in the last syllable therefore giving the two names different visual appearances. Brilinta Ritalin In addition, lowercase letter 't' is in a different position in both names and helps to differentiate the two names. Brilinta is a single-strength product (i.e., 90 mg) thus the strength may be omitted from a prescription. Conversely, Ritalin is a multiple strength product (i.e., 5 mg. 10 mg, 20 mg) that requires a strength for prescribing. In addition, there are no overlapping strengths between the two products. If a prescription for Brilinta is misinterpreted as Ritalin. The dispenser would have to question the order considering a single dose of Brilinta (i.e. 90 mg) exceeds the maximum daily dosage for Ritalin (i.e., 60). If a prescription for Ritalin is misinterpreted as Brilinta, the dispenser would have to question the order considering Brilinta is not supplied in a strength that will achieve a usual dose of Ritalin (10 mg to 60 mg/day).

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22433	ORIG-1	ASTRAZENECA LP	AZD6140

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

/s/

Latoya S TOOMBS
02/16/2010

CARLOS M MENA-GRILLASCA
02/16/2010

DENISE P TOYER
02/16/2010

CAROL A HOLQUIST
02/17/2010

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

Date:	April 14, 2011
Application Type/Number:	NDA 022433
Through:	Irene Z. Chan, Pharm.D, BCPS, Team Leader Carol A. Holquist, RPh, Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	L. Shenee' Toombs, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Brilinta (Ticagrelor) Tablets 90 mg
Applicant:	AstraZeneca LP
OSE RCM #:	2011-94

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

CONTENTS

1 INTRODUCTION

This re-assessment of the proprietary name responds to a proprietary name request submitted January 24, 2011. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Brilinta, acceptable in OSE Review #2009-2287 dated February 16, 2010, OSE Review #2010-645 dated July 2, 2010 and OSE Review # 2010-2010 dated December 1, 2010.

1.2 REGULATORY HISTORY

This application was originally submitted on November 12, 2009 by Astra Zeneca. A complete response was issued by the Agency on December 16, 2010 due to the need of further detailed analyses on the clinical studies. The Applicant has addressed the clinical concerns and resubmitted the application on January 20, 2011.

2 METHODS AND RESULTS

For the proposed proprietary name, DMEPA staff searched a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. We used the same search criteria that were used in OSE Review #2009-2287 for the proposed proprietary name, Brilinta. Since none of the proposed product characteristics were altered we did not re-evaluate previous names of concern. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates.

The searches of the databases yielded no new names thought to look similar to Brilinta and represent a potential source of drug name confusion. DMEPA staff also did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name Brilinta, as of April 12, 2011.

3 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Brilinta, is not vulnerable to name confusion that could lead to medication errors. DDMAC had no concerns regarding the proposed name from a promotional perspective. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Brilinta, for this product at this time. The Applicant will be informed by letter.

DMEPA considers this a final review; however if approval of the NDA is delayed beyond the goal date of July 20, 2011, the Division of Cardiovascular and Renal Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

4 REFERENCES

1. **OSE review #2009-2287 Proprietary Name Review of Brilinta; Toombs, L. Shenee'.**
2. **OSE review #2010-645 Proprietary Name Review of Brilinta; Toombs, L. Shenee'.**
3. **OSE review #2010-2010 Proprietary Name Review of Brilinta; Baksh, Charlene.**
4. ***Drugs@FDA (***http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm***)***
   Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.
5. ***USAN Stems (***http://www.ama-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.
6. ***Division of Medication Error Prevention and Analysis proprietary name requests***
   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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

/s/

LATOYA S TOOMBS
04/14/2011

IRENE Z CHAN
04/14/2011

CAROL A HOLQUIST
04/14/2011

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:	July 2, 2010
To:	Norman Stockbridge, MD, Director Division of Cardiovascular and Renal Products
Through:	Carlos Mena-Grillasca, RPh, Team Leader Denise Toyer, PharmD, Deputy Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	L. Shenee' Toombs, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Proprietary Name Review
Drug Name(s):	Brilinta (Ticagrelor) Tablets 90 mg
Application Type/Number:	NDA 022433
Applicant:	AstraZeneca LP
OSE RCM #:	2010-645

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

1 INTRODUCTION

This re-assessment of the proposed proprietary name, Brilinta, responds to the anticipated approval of NDA 022433 within 90 days from the date of this review. The Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Brilinta, acceptable in OSE Review #2009-2287, dated February 16, 2010. The Division of Drug Marketing, Advertising and Communication (DDMAC) found the name acceptable from a promotional perspective on December 03, 2009. Furthermore the review Division did not have any concerns with the proposed name, Brilinta, during our initial review.

2 METHODS

For the proposed proprietary name, DMEPA staff search a standard set of databases and information sources (see Section 6) to identify names with orthographic and/or phonetic similarity to the proposed name that have been approved since the completion of the previous OSE proprietary name review. We used the same search criteria outlined in OSE Review #2009-2287, for the proposed proprietary name, Brilinta. None of Brilinta's product characteristics have been altered since our previous review thus, we did not re-evaluate previous names of concern.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proposed proprietary name, and focuses on the avoidance of medication errors.

3 RESULTS AND DISCUSSION

DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of June 21, 2010.

The searches of the databases listed in section 5 identified one additional name thought to sound similar to Brilinta and represents a potential source of drug name confusion. The name thought to sound similar to Brilinta was: (b) (4)***.

FMEA analysis determined that the phonetic similarity between Brilinta and (b) (4)*** was unlikely to result in medication errors for the reasons presented in Appendix A.

4 CONCLUSIONS AND RECOMMENDATIONS

The Proprietary Name Risk Assessment indicates that the proposed name, Brilinta, is not vulnerable to name confusion that could lead to medication errors, nor is the name considered promotional. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) has no objection to the proprietary name, Brilinta, 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 Cardiovascular and Renal Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

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

5 REFERENCES

1. Toombs, L. OSE Review #2009-2287: Proprietary Name Review for Brilinta. February 16, 2010.

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 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.

APPENDICIES

Appendix A: Products with multiple differentiating product characteristics

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)	Differentiating product characteristics
Brilinta **(Ticagrelor)** **Tablets**		**90 mg**	**180 mg orally once, followed by 90 mg orally twice daily**	
(b) (4)				

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22433	ORIG-1	ASTRAZENECA LP	AZD6140

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

/s/

Latoya S TOOMBS
07/01/2010

CARLOS M MENA-GRILLASCA
07/02/2010

DENISE P TOYER
07/07/2010