

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**BLA 125160/0**

**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: April 3, 2008

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Subject: Final Proprietary Name, Label, and Labeling Review

Drug Name(s): Cimzia (Certolizumab pegol)

Application Type/Number: BLA 125160/0

Applicant/sponsor: UBC, Inc.

OSE RCM #: 2008-458

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

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## EXECUTIVE SUMMARY

The results of the Proprietary Name Risk Assessment found that the proposed name, Cimzia, has some similarity to other proprietary and proper drug names, but the findings of the FMEA indicates that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors. Thus, DMETS does not object to the use of the proprietary name Cimzia for this product.

However; if any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed container labels and carton labeling appears to be vulnerable to confusion that could lead to medication errors. DMETS believes the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations in Section 6 that aim at reducing the risk of medication errors.

## 1 BACKGROUND

### 1.1 INTRODUCTION

This review is in response to a request from the Division of Gastroenterology Products (HFD-180) for a final assessment of the proprietary name, Cimzia, regarding potential name confusion with other proprietary or established drug names. DMETS previously reviewed and had no objection to the proprietary name, Cimzia, in OSE reviews # 05-0207 dated August 18, 2005, #06-0199 dated August 4, 2006, and #2007-1693 dated August 14, 2007.

Additionally, the container labels, carton and insert labeling were provided for evaluation to identify areas that could lead to medication errors. DMETS previously reviewed and recommended revisions to the container label, carton, and insert labeling of Cimzia in OSE review # 06-0199 dated August 4, 2006.

### 1.2 PRODUCT INFORMATION

Cimzia (certolizumab pegol) lyophilized powder for injection is a recombinant humanized antibody Fab' fragment with specificity for human tumor necrosis factor alpha (TNF $\alpha$ ). Cimzia is indicated for reducing signs and symptoms of Crohn's disease and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. The recommended adult dose of Cimzia is 400 mg given as two subcutaneous injections of 200 mg at weeks 0, 2, and 4. In patients who obtain a clinical response, the recommended maintenance regimen is 400 mg every four weeks. Cimzia should be prepared and administered by a health care professional.

Cimzia will be supplied in a carton that contains all of the materials required to reconstitute and inject the drug:

1. 2 vials of Cimzia lyophilized powder for injection, 200 mg/vial
2. Medication Guide
3. 2 kits/trays to hold the reconstitution supplies, each containing:
  - 1 vial of Sterile Water for Injection, USP, 1 mL
  - 1 single-use plastic syringe
  - 8 alcohol swabs
  - 2 reconstitution needles
  - 1 dosing needle

Cimzia should be stored in the refrigerator at 2 to 8 °C.

Prior to reconstitution, Cimzia should be brought to room temperature to facilitate dissolution. However, reconstituted Cimzia should not be left at room temperature for more than 2 hours prior to reconstitution. Once reconstituted, Cimzia can be stored up to 24 hours in the refrigerator.

Two vials of Cimzia 200 mg are reconstituted for each 400 mg dose. Using appropriate aseptic technique, each vial of Cimzia is reconstituted with 1 mL of Sterile Water for Injection, USP (SWFI), using the syringe with a 20 gauge needle. The vial should be gently swirled without shaking so that the lyophilized powder comes into contact with the SWFI. The vials should be left undisturbed to fully reconstitute, which may take as long as 30 minutes. Upon reconstitution, Cimzia becomes a clear to opalescent colorless to pale yellow liquid with no visible particulates or gels in solution. Using a new 20 gauge needle for each vial, the reconstituted solution should be drawn into a separate syringe for each vial, resulting in two syringes each containing 1 mL of Cimzia (200 mg). The 20 gauge needles on each syringe should then be switched to 23 gauge needles. The 400 mg dose is then administered by injecting the full contents of each syringe subcutaneously into separate sites on the abdomen or thigh. The two 200 mg subcutaneous injections comprise the 400 mg dose.

## 2 METHODS AND MATERIALS

This section consists of two sub-sections which describe the methods and materials used by DMETS medication error staff conducting a proprietary name risk assessment (see 2.1 Proprietary Name Risk Assessment) and label, labeling, and/or packaging risk assessment (see 2.2 Container, Carton Label, and Insert Label Risk Assessment). The primary focus for both of the assessments is to identify and remedy potential sources of medication error prior to drug approval. DMETS 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.<sup>1</sup>

### 2.1 PROPRIETARY NAME RISK ASSESSMENT

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

For the proprietary name, Cimzia, the medication error staff of DMETS search a standard set of databases and information sources to identify names with orthographic and phonetic similarity (see Sections 2.1.1 for detail) and held an CDER Expert Panel discussion to gather professional opinions on the safety of the proposed proprietary name (see 2.1.1.2). DMETS normally conducts internal CDER prescription analysis studies and, when provided, external prescription analysis studies results are considered and incorporated into the overall risk assessment. However, since this name was previously evaluated, CDER prescription analysis studies were not conducted upon re-review of Cimzia.

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 (see detail 2.1.2). The overall risk assessment is based on the findings of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail.<sup>2</sup> FMEA is used to analyze whether the drug names identified with look- or sound-alike similarity to the proposed name

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

<sup>2</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

could cause confusion that subsequently leads to medication errors in the clinical setting. DMETS uses the clinical expertise of the medication error staff to anticipate the conditions of the clinical setting that the product is likely to be used in 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. As such, the Staff considers the product characteristics associated with the proposed drug throughout the risk assessment, since 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 drug name include, but are not limited to established name of the proposed product, the proposed indication, 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, DMETS 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.<sup>3</sup>

For this fourth and final review of the proposed name, Cimzia, the Safety Evaluator additionally consulted the three previous reviews for Cimzia; OSE reviews # 05-0207 dated August 18, 2005, #06-0199 dated August 4, 2006, and #2007-1693 dated August 14, 2007.

### **2.1.1 Search Criteria**

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted as outlined in Appendix A.

For this review, particular consideration was given to drug names beginning with the letter 'C' 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.<sup>4,5</sup>

To identify drug names that may look similar to Cimzia, the Staff also consider the orthographic appearance of the name on lined and unlined orders. Specific attributes taken into consideration include the length of the name (six letters), downstrokes (one, lower case scripted letter 'z'), and dotted letters (two, lower case letter 'i'). Additionally, several letters in Cimzia may be vulnerable to ambiguity when scripted, including the capital letter 'C' may appear as capital 'A'; lower case 'i' may look like lower case 'e', or 'l'; lower case 'm' may look like lower case 'n'; lower case letter 'z' may appear as lower case 'g' or 'y' or 'p'; and lower case 'a' may appear as lower case 'o' or 'ce'. As such, the Staff also considers these alternate appearances when identifying drug names that may look similar to Cimzia.

When searching to identify potential names that may sound similar to Cimzia, the Medication Error Staff search for names with similar number of syllables (3), stresses (sim-Z-uh or sim-zi-ah or kim-Z-uh or kim-zi-ah), and placement of vowel and consonant sounds. The Sponsor's intended pronunciation of the

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<sup>3</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

<sup>4</sup> Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at <http://www.ismp.org/Tools/confuseddrugnames.pdf>

<sup>5</sup> Kondrack, G and Dorr, B. Automatic Identification of Confusable Drug Names. Artificial Intelligence in Medicine (2005)

proprietary name could not be expressly taken into consideration, as this was not provided with the proposed name submission.

The Staff also consider the product characteristics associated with the proposed drug throughout the identification of similar drug names, since the product characteristics of the proposed drug ultimately determine the use of the product in the clinical practice setting. For this review, the Medication Error Staff were provided with the following information about the proposed product: the proposed proprietary name (Cimzia) the proper name (certolizumab pegol), proposed indication (treatment of Crohn's disease), strength (200 mg/vial), dose (400 mg), frequency of administration (every 2 weeks during initial dosing for 3 doses, then every 4 weeks), route (subcutaneous injection), and dosage form (lyophilized powder for injection). Appendix A provides a more detailed listing of the product characteristics the Medication Error Staff generally take into consideration.

Lastly, the Medication Error Staff also consider the potential for the proposed 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. As such, these broader safety implications of the name are considered and evaluated throughout this assessment and the Medication Error Staff provide additional comments related to the safety of the proposed name or product based on their professional experience with medication errors.

#### **2.1.1.1 Database and information sources**

The proposed proprietary name, Cimzia, was provided to the medication error staff of DMETS to conduct a search 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 Cimzia using the criteria outlined in 2.1.1. A standard description of the databases used in the searches is provided in Section 7. To complement the process, the Medication Error 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 Medication Error Staff review the USAN stem list to determine if any USAN stems are present within the proprietary name. The findings of the individual Safety Evaluators were then pooled and presented to the Expert Panel.

#### **2.1.1.2 CDER Expert Panel Discussion**

An Expert Panel Discussion is held by DMETS to gather CDER professional opinions on the safety of the product and the proprietary name, Cimzia. Potential concerns regarding drug marketing and promotion related to the proposed names are also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representatives from the Division of Drug Marketing, Advertising, and Communications (DDMAC).

The pooled results of the medication error staff were presented 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 Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

#### **2.1.2 Safety Evaluator Risk Assessment of the Proposed Proprietary Name**

Based on the criteria set forth in Section 2.1, the Safety Evaluator Risk Assessment applies their individual expertise gained from evaluating medication errors reported to FDA to conduct a Failure Modes and Effects Analysis and provide an overall risk 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.<sup>6</sup> When applying FMEA to assess the risk of a proposed proprietary name, DMETS seeks to evaluate the potential for a proposed name to be confused with another drug name as a result of the name confusion and 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 look- or sound-alike 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 Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is not yet marketed, the Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product characteristics listed in Appendix A. 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 evaluation, and studies, and identifies potential failure modes by asking: "Is the name Cimzia 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 Cimzia 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 possess similarity that would cause confusion at any point in the medication use system and the name is eliminated from further review.

In the second stage of the Risk Assessment, all potential failure modes are evaluated 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 ultimately not be a source of medication errors in the usual practice setting, the name is eliminated 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 that an alternate proprietary name be used. In rare instances, the FMEA findings may provide other risk-reduction strategies, such as product reformulation to avoid an overlap in strength or an alternate modifier designation may be recommended as a means of reducing the risk of medication errors resulting from drug name confusion.

DMETS will object to the use of proposed proprietary name when the one or more of the following conditions are identified in the Safety Evaluator's Risk Assessment:

1. 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 trade name or otherwise. [21 U.S.C 321(n); see also 21 U.S.C. 352(a) & (n)].
2. DMETS 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)].

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<sup>6</sup> Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

3. FMEA identifies potential for confusion between the proposed proprietary name and other proprietary or established drug names, and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
4. The proposed proprietary name contains an USAN stem, particularly in a manner that is contradictory to the USAN Council's definition.
5. Medication Error Staff identify a potential source of medication error within the proposed proprietary name. 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.

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

If none of these conditions are met, then DMETS will not object to the use of the proprietary name. If any of these conditions are met, then DMETS will object to the use of the proprietary name. The threshold set for objection to the proposed proprietary name may seem low to the Sponsor; however, the safety concerns set forth in criteria 1 through 5 are supported either by FDA Regulation or by external healthcare authorities, including the IOM, WHO, Joint Commission, and ISMP, who have examined medication errors resulting from look- or sound-alike drug names and called for Regulatory Authorities to address the issue prior to approval.

Furthermore, DMETS 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, can be identified and remedied prior to approval to avoid patient harm.

Additionally, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to remedy post-approval. Educational efforts and so on are low-leverage strategies that have proven to have limited effectiveness at alleviating the medication errors involving drug name confusion. Higher-leverage strategies, such as drug name changes, have been undertaken 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 the approving the error-prone proprietary name. Moreover, even after Sponsor's have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioner's vocabulary, and as such, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMETS 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 limitations of the process).

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

## 2.2 LABEL AND LABELING RISK ASSESSMENT

The label and labeling of a drug product are the primary means by which practitioners and patients (depending on configuration) interact with the pharmaceutical product. The carton and container labels communicate critical information including proprietary and established name, strength, form, container quantity, expiration, and so on. The insert labeling is intended to communicate to practitioners all information relevant to the approved uses of the drug, including the correct dosing and administration.

Given the critical role that the label and labeling has in the safe use of drug products, it is not surprising that 33 percent of medication errors reported to the USP-ISMP Medication Error Reporting Program may be attributed to the packaging and labeling of drug products, including 30 percent of fatal errors.<sup>7</sup>

Because DMETS staff analyze reported misuse of drugs, DMETS staff are able to use this experience to identify potential errors with all medication similarly packaged, labeled or prescribed. DMETS uses FMEA and the principles of human factors to identify potential sources of error with the proposed product labels and insert labeling, and provided recommendations that aim at reducing the risk of medication errors.

For this product the Sponsor submitted via e-mail on March 24, 2008, the following labels and insert labeling for DMETS review (see Appendix F, G, and H for images):

- Container Label for Cimzia: 200 mg/vial
- Container Label for Diluent (Sterile Water for Injection, USP): 1 mL
- Tray Labeling
- Commercial Carton Labeling: 400 mg kit (2 vials of 200 mg Cimzia)
- Sample Carton Labeling: 400 mg kit (2 vials of 200 mg Cimzia)
- Cimzia Administration Booklet (1 page-CIA70014)
- Insert Labeling (no image)
- Medication Guide (no image)

## 3 RESULTS

### 3.1 PROPRIETARY NAME RISK ASSESSMENT

#### 3.1.1 Database and information sources

DMETS conducted a search of the internet, several standard published databases and information sources (see Section 7 References) for existing drug names which sound-alike or look-alike to Cimzia to a degree where potential confusion between drug names could occur and result in medication errors in the usual clinical practice settings. For this final review, 22 names were identified as having some similarity to the name Cimzia: Alinia, Avinza, Alimta, Climara, Certiva, Amitiza, Aredia, Arava, Asimia, Avandia, \_\_\_\_\_, Amytal, Amrix, Campral, Canasa, Cesia, Anexsia, Compro, Avapro, and Amziax. Eleven of the names identified in the three previous DMETS reviews as having some similarity

<sup>7</sup> Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006. p275.

to the proposed name Cimzia are listed in Appendix B. These names were not determined to pose a risk for error with Cimzia.

The thirteen names not previously reviewed are: Alimta, Certiva, Aredia, Arava, Avandia, Amytal, Campral, Canasa, Cesia, Anexsia, Compro, and Avapro. All thirteen names were thought to look like Cimzia. One name (Cesia) was also thought to sound similar to Cimzia.

### ***3.1.2 Expert panel discussion***

The Expert Panel reviewed the pool of names identified by DMETS staff (see section 3.1.1. above). DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name.

### ***3.1.3 Safety evaluator risk assessment***

A total of thirteen new names were analyzed to determine if the drug names could be confused with Cimzia and if the drug name confusion would likely result in a medication error.

All of the identified names were determined to have some orthographic and/or phonetic similarity to Cimzia, and thus determined to present some risk of confusion. However, subsequent failure modes and effects analysis determined that the name similarity between Cimzia and the identified names was unlikely to result in medication errors for the thirteen products.

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For the remaining 12 names, FMEA determined that medication errors were unlikely because they do not overlap in strength, dosage, or indication of use and have minimal orthographic and/or phonetic similarity to Cimzia (See Appendix D).

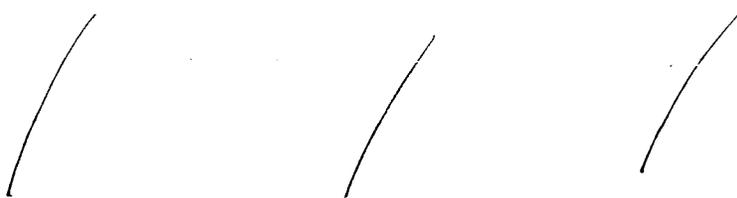
## **3.2 LABEL AND LABELING RISK ASSESSMENT**

Review of the container labels and carton labeling identified several areas of vulnerability that could lead to medication error, specifically with respect to the proper use of the product, product strength, and route of administration.

### ***3.2.1 Container Labels***



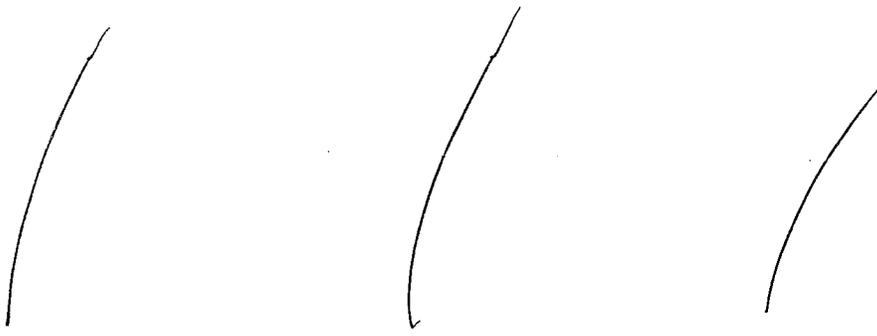
### ***3.2.2 Carton Labeling***





### 3.2.3 *Insert Labeling*

The Dosage and Administration section of the Highlights of Prescribing Information is not consistent with the Dosage and Administration section under the Full Prescribing Information. The text “as two subcutaneous injections of 200 mg” is lacking in the Highlights of Prescribing Information. Additionally, there is a space missing between the number and the unit of measure in the dose reference of the Highlights section (e.g., should be printed as 400 mg and not 400mg).



## 4 DISCUSSION

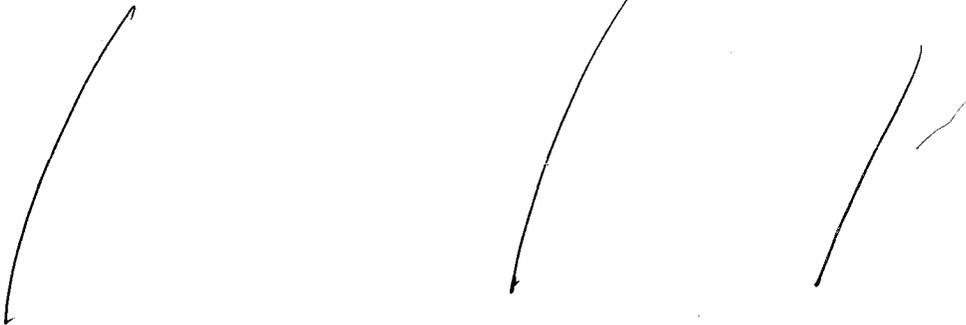
The results of the Proprietary Name Risk Assessment found that the proposed name, Cimzia, has some similarity to other proprietary and established drug names, but the findings of the FMEA process indicate that the proposed name does not appear to be vulnerable to name confusion that could lead to medication errors.

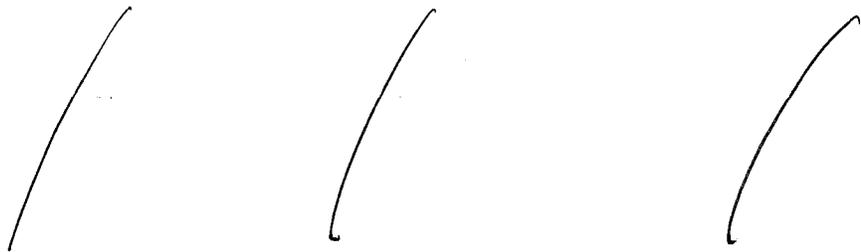
The results of the Label and Labeling Risk Assessment found that the presentation of information and design of the proposed container labels and carton labeling appears to be vulnerable to confusion that could lead to medication errors. Specifically, DMETS notes problems with the prominence, presentation, and consistency of information that is vital for the safe use of the drug product.

### 4.1 CONTAINER LABEL



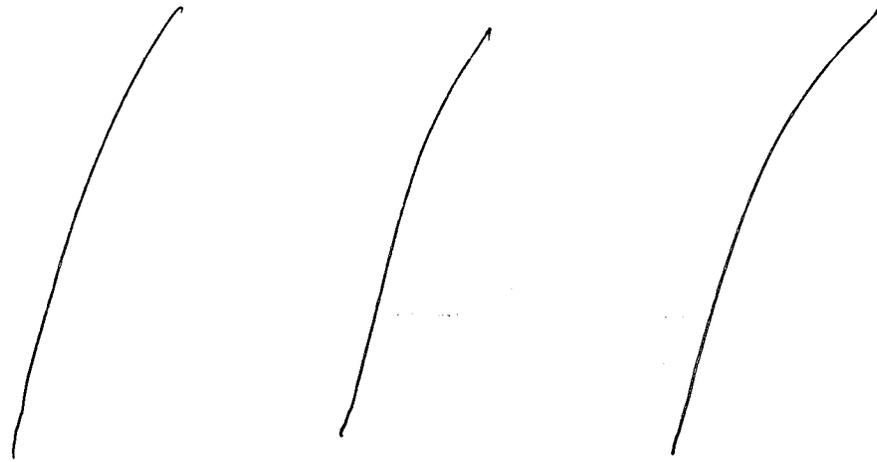
### 4.2 CARTON LABELING





### 4.3 INSERT LABELING

When evaluating the insert labeling, we noted information that is presented in an inconsistent or otherwise confusing manner which may lead to confusion or inappropriate or incorrect dosing. The Dosage and Administration section of the Highlights of Prescribing Information omits important information regarding the dose and administration that is included in the Dosage and Administration section of the Full Prescribing Information. Specifically, the text that Cimzia is given “as two subcutaneous injections of 200 mg” is not included in the Highlights of Prescribing Information. It is important for healthcare professionals to understand that two injections are needed to provide a single dose. If this information is excluded from the Highlights section, it increases the possibility for confusion and may result in the patient only receiving one injection, or half the recommended dose.



### 5 CONCLUSIONS

The Proprietary Name Risk Assessment findings indicate that the proposed name, Cimzia, does not appear to be vulnerable to name confusion that could lead to medication errors. As such, DMETS does not object to the use of the proprietary name, Cimzia, for this product. However, if any of the proposed product characteristics as stated in this review are altered prior to approval of the product; DMETS rescinds this Risk Assessment finding, and recommends that the name 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. Additionally, if the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

The Label and Labeling Risk Assessment findings indicate that the presentation of information and design of the proposed container labels and carton labeling introduces vulnerability to confusion that could lead to medication errors. Specifically, DMETS notes problems with the prominence, presentation, and consistency of information that is vital to the safe use of the product. DMETS believes the risks we have identified can be addressed and mitigated prior to drug approval, and provides recommendations in Section 6 that aim at reducing the risk of medication errors.

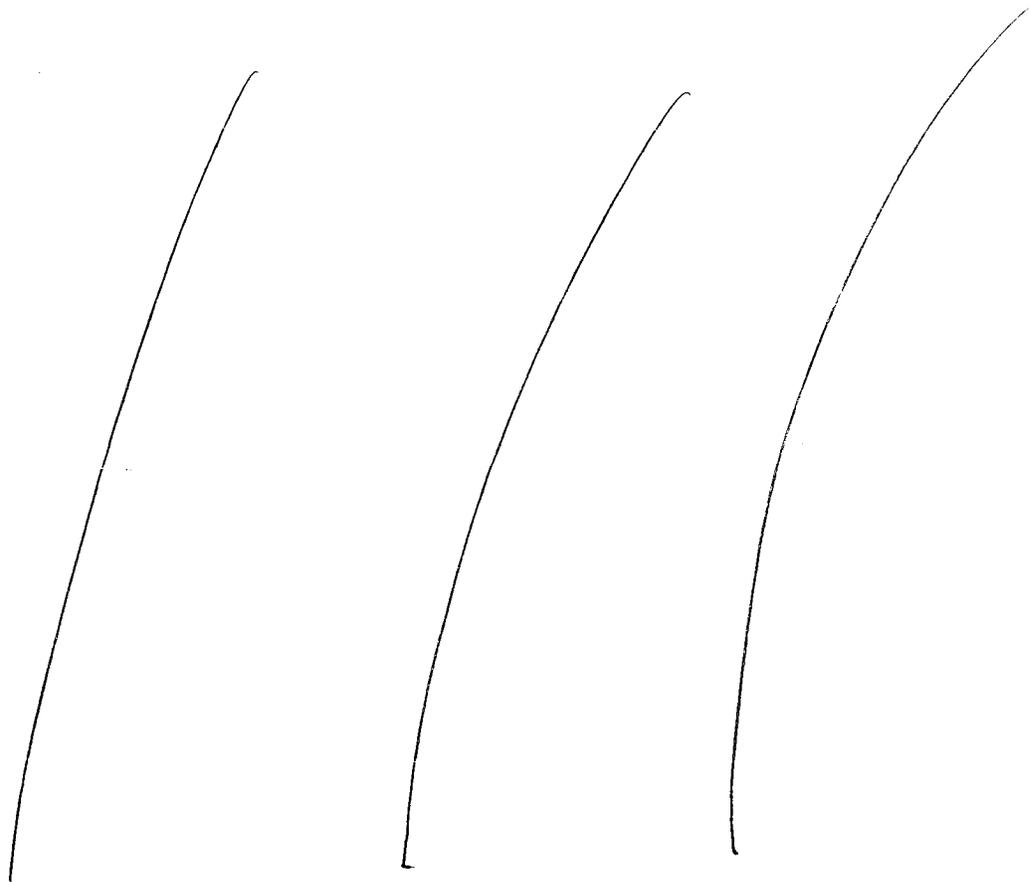
DMETS would appreciate feedback on the final outcome of this review. We would be willing to meet with the Division for further discussion, if needed. Please copy DMETS on any communication to the sponsor with regard to this review. If you have further questions or need clarifications, please contact Cheryle Milburn, project manager, at 301-796-2084.

## **6 RECOMMENDATIONS FOR THE SPONSOR**

### **6.1 Proprietary name:**

DMETS has no objections to the use of the proprietary name Cimzia for this product. If any of the proposed product characteristics as stated in this review are altered prior to approval of the product, DMETS rescinds this Risk Assessment finding, and recommends that the name be resubmitted for review. If the product approval is delayed beyond 90 days from the date of this review, the proposed name must be resubmitted for evaluation.

### **6.2 Labels and Labeling:**



1  
\_\_\_\_\_ Page(s) Withheld

✓  
\_\_\_\_\_ Trade Secret / Confidential

\_\_\_\_\_ Draft Labeling

\_\_\_\_\_ Deliberative Process

## 7 REFERENCES

1. ***Micromedex Integrated Index*** (<http://weblern>)

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

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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. This is a database which was created for DMETS, FDA.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO*** (<http://weblern>)

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

4. ***AMF Decision Support System [DSS]***

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

5. ***Division of Medication Errors and Technical Support proprietary name consultation requests***

This is a list of proposed and pending names that is generated by DMETS 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 and generic drugs and therapeutic biological products; prescription and over-the-counter human drugs and therapeutic biologicals, discontinued drugs and "Chemical Type 6" approvals.

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

Provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. ***United States Patent and Trademark Office*** <http://www.uspto.gov>.

Provides information regarding patent and trademarks.

9. ***Clinical Pharmacology Online*** (<http://weblern>)

Contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. Provides a keyword search engine.

**10. Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com)**

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

**11. Natural Medicines Comprehensive Databases (<http://weblern/>)**

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

**12. Stat!Ref (<http://weblern/>)**

Contains full-text information from approximately 30 texts. 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>)**

List contains all the recognized USAN stems.

**14. Red Book Pharmacy's Fundamental Reference**

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

**15. Lexi-Comp ([www.pharmacist.com](http://www.pharmacist.com))**

A web-based searchable version of the Drug Information Handbook.

**16. Medical Abbreviations Book**

Contains commonly used medical abbreviations and their definitions.

## APPENDICES

### Appendix A:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMETS also compare the spelling of the proposed proprietary name with the proprietary and proper name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine 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* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has led to medication errors. The Medication Error Staff apply their 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, DMETS will consider the Sponsor's intended pronunciation of the proprietary name. However, because the Sponsor has little control over how the name will be spoken in practice, DMETS also considers a variety of pronunciations that could occur in the English language.

**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	<ul style="list-style-type: none"> <li>Identical prefix</li> <li>Identical infix</li> <li>Identical suffix</li> <li>Length of the name</li> <li>Overlapping product characteristics</li> </ul>	<ul style="list-style-type: none"> <li>• Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>• Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	<ul style="list-style-type: none"> <li>Similar spelling</li> <li>Length of the name</li> <li>Upstrokes</li> <li>Downstrokes</li> <li>Cross-strokes</li> <li>Dotted letters</li> </ul>	<ul style="list-style-type: none"> <li>• Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

		Ambiguity introduced by scripting letters Overlapping product characteristics	
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"> <li>Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

**Appendix B:** Names identified in 3 previous DMETS reviews as having some similarity to Cimzia

Proprietary Name	Similarity to Cimzia
Alinia	Look
Avinza	Look
— *** (approved as Pexeva)	Look
Amrix	Look
Ambien	Look
Climara	Look
Viagra	Look
Cimetidine	Look
Sinsia (South Korea)	Look and Sound

Amziar (Argentina)	Look
Amicor	Look
Amicar	Look
Omacor	Look
— ***	Look and Sound
— **	Look
— ***	Look
Camila	Look
Gemzar	Look
Amitiza	Look
Centrax	Look

\*\*\*These names are proprietary and confidential information that should not be released to the public.

**Appendix C:** Proposed proprietary names for products not approved or approved with another name.

Proprietary Name	Similarity to Cimzia
— **	Look

\*\*\*These names are proprietary and confidential information that should not be released to the public.

**Appendix D:** Products with no numerical overlap in strength and dose.

Product name with potential for confusion	Similarity to Proposed Proprietary Name	Strength	Usual Dose (if applicable)
Cimzia (certolizumab pegol) lyophilized powder for injection		200 mg/vial	400 mg via two subcutaneous injections of 200 mg every two weeks (during initial dosing for 3 doses) or every 4 weeks (during maintenance dosing)
Alimta (pemetrexed)	Look	Lyophilisate powder for injection: 100 mg, 500 mg	500 mg/m <sup>2</sup> (~ 700 mg to 1000 mg) over 10 minutes plus Cisplatin on day 1 of a 21 day cycle. (dose may be adjusted based on toxicity of previous cycles)  Folic acid, B-12, and dexamethasone may be ordered concurrently
Aredia (pamidronate disodium)	Look	Injection: 3 mg/mL, 6 mg/mL, 9 mg/mL  Lyophilized powder for injection: 30 mg, 90 mg	Depending on the indication, one time infusions of 30 mg, 60 mg, or 90 mg over 2-4 hours or longer. A regimen of 30 mg infused daily for 3 days is also used.
Arava (leflunomide)	Look	Oral tablets: 10 mg, 20 mg	100 mg daily for three days, then 20 mg daily as maintenance dose.
Avandia (rosiglitazone maleate)	Look	Oral tablets: 2 mg, 4 mg, 8 mg	2-8 mg orally once daily. May also be given in divided doses twice daily.
Amytal (amytal sodium)	Look	Powder for injection: 250 mg/vial, 500 mg/vial	Intravenous or intramuscular injection: The maximum single dose for an adult is 1 g.  Sedative: 30 to 50 mg given 2 or 3 times daily  Hypnotic: 65 to 500 mg at bedtime.
Campral (acamprosate calcium)	Look	Delayed-release tablets: 333 mg	One or two 333 mg tablets given 3 times daily
Canasa (mesalamine)	Look	Rectal suppositories: 1000 mg	One 1,000 mg suppository daily at bedtime. Retain the suppository in the rectum for 1 to 3 hours or more if possible to achieve maximum benefit.

			Usual course of therapy is 3 to 6 weeks.
Cesia (desogestrel/ethinylestradiol)	Look and Sound	21 day triphasic oral contraceptive	One tablet orally once daily
Anexsia (hydrocodone bitartrate/acetaminophen)	Look	Oral tablets: 10 mg/660 mg, 7.5 mg/ 650 mg, 7.5 mg/325 mg, 5 mg/500 mg, 5 mg/325 mg)	1 to 2 tablets (hydrocodone 5 to 10 mg; acetaminophen 325 to 660 mg) every 4 to 6 hours as needed.
Compro (prochlorperazine)	Look	Rectal suppositories: 25 mg	25 mg rectally twice daily or as needed
Avapro (irbesartan)	Look	Oral tablets: 75 mg, 150 mg, 300 mg	One tablet once daily
Certiva (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed; DTaP)	Look	Vaccine: 15 Doses (7.5 ml)	A 0.5 ml intramuscular injection administered at 2, 4, and 6 months of age, at intervals of six to eight weeks, with a fourth dose given at 15-20 months of age. The interval between the third and fourth doses should be at least 6 months.  Should not be administered to those greater than 7 years of age.

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**MEMORANDUM**

**Division of Medication Errors and Technical Support  
Office of Surveillance and Epidemiology  
HFD-420; WO22, Mail Stop 4447  
Center for Drug Evaluation and Research**

**To:** Dan Shames, MD  
Director, Division of Gastroenterology Products  
HFD-180.

**Through:** Linda Y. Kim-Jung, PharmD, Team Leader *WMC 8/24/07*  
Carol A. Holquist, RPh, Director *CAH 8/24/07*  
Division of Medication Errors and Technical Support, HFD-420

**From:** Loretta Holmes, BSN, PharmD, Safety Evaluator *LH 8/24/07*  
Division of Medication Errors and Technical Support, HFD-420

**Date:** August 14, 2007

**Subject:** **DMETS Proprietary Name Review**  
Drug: Cimzia (Certolizumab Pegol) Lyophilized Powder  
BLA#: 125160/0  
Sponsor: UBC, Inc.

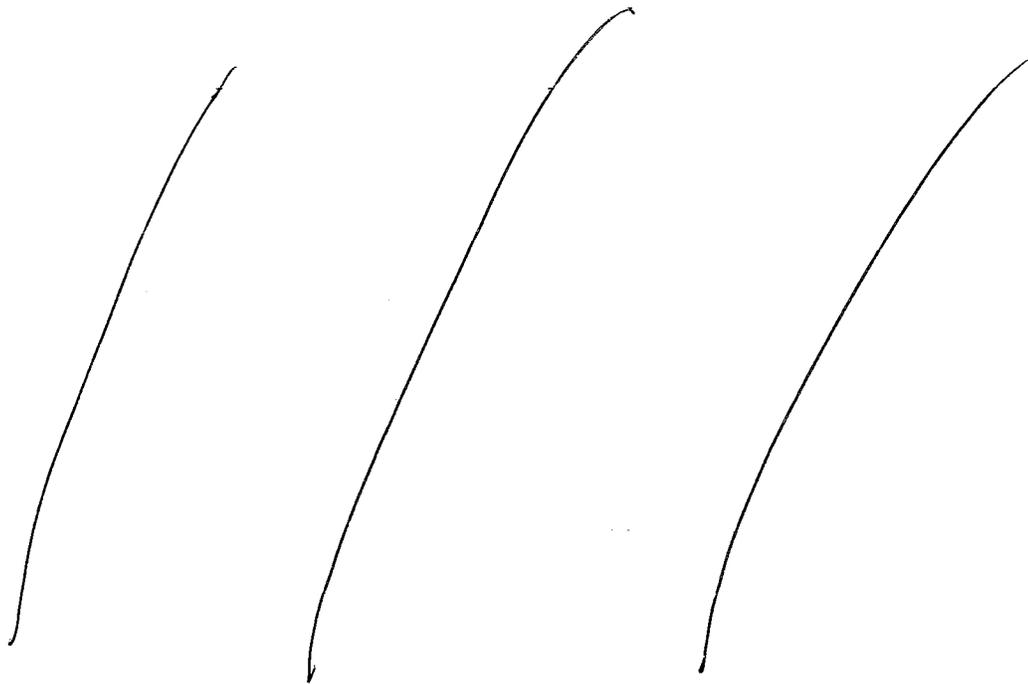
**Review #:** 2007-1693

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

This memo is written in response to a request from the Division of Gastroenterology Products (HFD-180) for a final review of the proposed proprietary name, Cimzia. DMETS provided label/labeling recommendations in OSE Review 06-0199, dated September 5, 2006. However, no updated revised labels/labeling were submitted with this review request.

Since completion of our last review, (OSE Review 06-0199), DMETS has identified five additional names (Gemzar, Amitiza, Centrax, \_\_\_\_\_, and Camila) as having the potential for look-alike and/or sound-alike similarities to Cimzia. After initial analysis of the five names, it was determined that Gemzar, Amitiza, and Centrax would not be considered further because they lacked convincing look-alike and/or sound-alike similarities to Cimzia in addition to having differentiating product characteristics such as indication of use, dose, and frequency of administration. Additionally, Centrax has been discontinued and there are no generic equivalents available. The remaining two names, \_\_\_\_\_ and Camila were evaluated further and are discussed in detail below:

- 1. */* */* */* */*
-



2. Camila was identified as a name with similar appearance to Cimzia. Camila (norethindrone) is an oral contraceptive. The recommended dose is 0.35 mg once daily and it is available in 0.35 mg tablets.

Camila and Cimzia may look similar because both names contain three letters that overlap and have the same location in both names (C A M I L A vs. C I M Z I A). The upstroke characteristic of the letter "l" in Camila and the downstroke characteristic of the letter "z" (when scripted in that manner) in Cimzia may help to differentiate the names.

Camila  
Cimzia

Additionally, Camila and Cimzia do not share any overlapping product characteristics other than the fact they are both available by prescription. These products differ in indication of use (contraception vs. Crohn's disease), dose (0.35 mg vs. 400 mg), dosage form (tablet vs. lyophilized powder), strength (0.35 mg vs. 200 mg/vial), route of administration (oral vs. subcutaneous), and frequency of administration (once daily vs. once at weeks 0, 2, and 4; then every 4 weeks) which may help to differentiate the products. For example, since Cimzia is administered parenterally, a prescription would likely state the route of administration. However, in the case where a prescription for these products is written with instructions to "use as directed" and the strength and dose are not specified (e.g., "Camila, use as directed" or "Cimzia, use as directed"), the orthographic differences between the names may help to

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

differentiate the products. Although there are some orthographic similarities between the names, the orthographic differences along with the different product characteristics will minimize the potential to confuse the name pair.

In summary, DMETS has no objections to the use of the proposed proprietary name, Cimzia. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. Additionally, the Division of Drug Marketing, Advertising, and Communications (DDMAC) finds the name, Cimzia, acceptable from a promotional perspective. DMETS also recommends implementation of the label/labeling revisions outlined in our previous review (OSE Review 06-0199).

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. Please copy DMETS on any correspondence to the sponsor pertaining to this issue. If you have further questions or need clarifications, please contact Cheryle Milburn, OSE Project Manager, at 301-796-2084.

**APPEARS THIS WAY  
ON ORIGINAL**

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT  
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY  
(DMETS; WO22, Mailstop 4447)

<b>DATE RECEIVED:</b> July 3, 2006	<b>DESIRED COMPLETION DATE:</b> September 28, 2006	<b>OSE REVIEW #:</b> 06-0199
<b>DATE OF DOCUMENT:</b> February 28, 2006		

**TO:** Brian Harvey, MD, PhD  
Director, Division of Gastroenterology Products  
HFD-180

**THROUGH:** Linda Y. Kim-Jung, PharmD, Team Leader  
Denise P. Toyer, PharmD, Deputy Director *DP.Toyer 9/5/06*  
Carol A. Holquist, RPh, Director *CA.Holquist 9/5/06*  
Division of Medication Errors and Technical Support

**FROM:** Loretta Holmes, PharmD, Safety Evaluator *LH 9/5/06*  
Division of Medication Errors and Technical Support

**PRODUCT NAME:** Cimzia  
(Certolizumab pegol) lyophilized powder  
200 mg vial

**BLA#:** 125160/0

**SPONSOR:** UBC, Inc.

- RECOMMENDATIONS:**
1. DMETS has no objections to the use of the proprietary name, Cimzia. This is considered a final decision. However, if the approval of this application is delayed beyond 90 days from the signature date of this document, the name must be re-evaluated. A re-review of the name will rule out any objections based upon approval of other proprietary or established names from the signature date of this document.
  2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review to minimize potential errors with the use of this product.
  3. DDMAC finds the proprietary name, Cimzia, acceptable from a promotional perspective

DMETS would appreciate feedback of the final outcome of this consult. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Diane Smith, Project Manager, at 301-796-0538.

Division of Medication Errors and Technical Support (DMETS)  
Office of Surveillance and Epidemiology  
White Oak Bldg #22, Mailstop 4447  
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: August 4, 2006  
BLA#: 125160/0  
NAME OF DRUG: Cimzia  
(Certolizumab pegol) lyophilized powder  
200 mg vial  
NDA HOLDER: UBC, Inc.

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

I. INTRODUCTION:

This consult was written in response to a request from the Division of Gastroenterology Products (HFD-180), for assessment of the proprietary name, Cimzia, regarding potential name confusion with other proprietary or established drug names. This is the second proprietary name review of Cimzia. In our first review, OSE Consult 05-0207, DMETS had no objections to the use of the proprietary name, Cimzia. The container label, carton and insert labeling were provided for review and comment.

PRODUCT INFORMATION

Cimzia is a recombinant humanized antibody Fab' fragment with specificity for human tumor necrosis factor alpha (TNF $\alpha$ ). Cimzia is indicated for \_\_\_\_\_

\_\_\_\_\_ The recommended adult dose of Cimzia is an induction regimen of 400 mg given as two subcutaneous injections at weeks 0, 2, and 4; followed by a maintenance regimen of 400 mg every 4 weeks. Cimzia will be supplied in kits, each containing two vials of Cimzia 200 mg lyophilized powder for reconstitution along with diluent, syringes, and other materials needed for preparing the medication for administration.

## II. RISK ASSESSMENT:

The medication error staff of DMETS conducted a search of several standard published drug product reference texts<sup>1,2</sup> as well as several FDA databases<sup>3,4</sup> for existing drug names which sound-alike or look-alike to, Cimzia, to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted<sup>5</sup>. The Saegis<sup>6</sup> Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches.

### A. EXPERT PANEL DISCUSSION (EPD)

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Cimzia. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. DDMAC finds the proprietary name, Cimzia, acceptable from a promotional perspective.
2. Since our previous review, the Expert Panel identified seven additional proprietary names that were thought to have the potential for confusion with Cimzia. These products are listed in Table 1 (see page 4), along with the dosage forms available and usual dosage.

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<sup>1</sup> MICROMEDEX Integrated Index, 2006, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

<sup>2</sup> Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.

<sup>3</sup> AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-06, and the electronic online version of the FDA Orange Book.

<sup>4</sup> Phonetic and Orthographic Computer Analysis (POCA)

<sup>5</sup> WWW location <http://www.uspto.gov/tmdb/index.html>.

<sup>6</sup> Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at [www.thomson-thomson.com](http://www.thomson-thomson.com)



D. SAFETY EVALUATOR RISK ASSESSMENT

DMETS did not have objections to the use of the proprietary name, Cimzia, in our first review, OSE Consult 05-0207 dated August 18, 2005. Since the completion of that review, the Expert Panel identified seven additional names (Amicar, Amicor, Omacor, Sinsia, and Amziax) as having the potential to cause name confusion with Cimzia. Three of these names are foreign drug names: Sinsia (serratiopeptidase in South Korea), Amziax (alprazolam in Argentina), and Amicor (amrinone injection in India). These names were not considered further because none are exact matches with Cimzia, they have limited areas of marketing, and/or there is limited information concerning the products. Additionally, a proposed proprietary name that is currently under review by the Agency, will not be further discussed due to minimal orthographic similarity, different product strengths and a different frequency of administration.

1. Amicar (aminocaproic acid) was identified as a name with similar appearance to Cimzia. Amicar is used to treat excessive bleeding due to fibrinolysis. The recommended intravenous dose is 4 gm, initially, followed by a continuous infusion of 1 gm per hour for 8 hours or until bleeding is controlled. The recommended oral dose is 5 gm, initially, followed by 1 gm per hour for 8 hours or until bleeding is controlled. Amicar is available in tablets (500 mg and 1000 mg), oral solution (250 mg/mL), and solution for injection (250 mg/mL).

The look-alike similarities between the names stem from the fact that the letters "Am" in Amicar may look similar to the letters "Ci" in Cimzia if the letter "A" is not completely closed when scripted. Additionally, the letter "c" in Amicar may look similar to the letter "z" in Cimzia if the letter "z" is written without a downstroke. However, there are many different product characteristics between Amicar and Cimzia such as dose (5 gm or 1 gm vs. 400 mg), strength (500 mg, 1000 mg, and 250 mg/mL vs. 200 mg/vial), route of administration (oral and intravenous vs. subcutaneous), frequency of administration (every 1 hour vs. one dose at weeks 0, 2, and 4, followed by one dose every 4 weeks), and indication of use (treatment of bleeding vs. Crohn's disease) which may help to differentiate the products. For example, a prescription for Amicar would have to specify the route of administration, dose, and frequency of administration because it can be given orally or by intravenous infusion and the initial and subsequent doses are different. Although there are some orthographic similarities between the names, the product differences will minimize the potential to confuse the name pair.

*Cimzia*  
*Amicar*

2. Omacor was identified as a name with similar appearance to Cimzia. Omacor contains omega-3-acid ethyl esters and is indicated for the reduction of very high triglycerides ( $\geq 500$  mg/dL) in adults. The recommended dose is 4 gm per day as a single 4 gm dose or as two 2 gm doses. Omacor is available as 1 gm capsules.

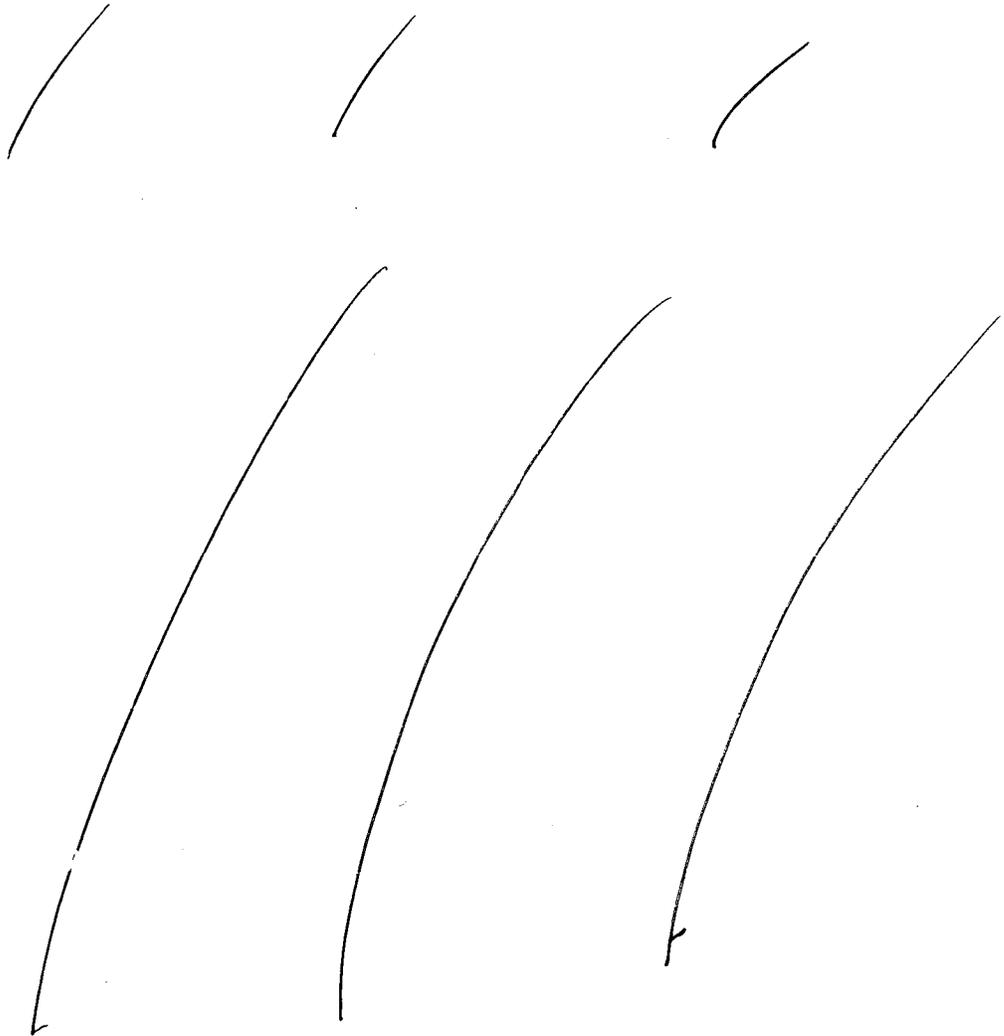
\*\*\*NOTE: This review contains proprietary and confidential information that should not be released to the public.\*\*\*

The orthographic similarities between the names is due to the fact that the letters "Ci" in Cimzia may look like the letter "O" in Omacor when the letters are placed close to one another and the dot over the letter "i" is omitted (see below).

*Omacor*  
*Cimzia*

Additionally, the letter "z" in Cimzia may look like the letter "c" in Omacor when it is scripted without the downstroke. However, these letters are in different positions in the names which may help to differentiate them. Omacor and Cimzia have different product characteristics such as strength (1 gm capsule vs. 200 mg per vial), dose (4 gm vs. 400 mg), and dosage form (capsule vs. powder for injection) that will help to differentiate the products. For example, an order for Cimzia is likely to specify the dose (since two vials are required) and route of administration (since it is administered parenterally) in order to be complete. Therefore, due to the different product characteristics, the potential to confuse Omacor and Cimzia is minimal.

3.



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