# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 202379Orig1s000

# 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**

# Proprietary Name Review

| | |
|---|---|
| Date: | April 13, 2011 |
| Reviewer(s): | Jibril Abdus-Samad, PharmD, Safety Evaluator<br>Division of Medication Error Prevention and Analysis |
| Team Leader | Todd Bridges, RPh, Acting Deputy Director<br>Division of Medication Error Prevention and Analysis |
| Division Director | Carol Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis |
| Drug Name(s): | Zytiga (Abiraterone Acetate) Tablets, 250 mg |
| Application Type/Number: | NDA 202379 |
| Applicant/sponsor: | Centocor Ortho Biotech, Inc. |
| OSE RCM #: | 2011-1195 |

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**CONTENTS**

## 1 INTRODUCTION

This review re-evaluates the proposed proprietary name, Zytiga, due to changes in the product characteristics. The anticipated approval of this NDA is within 90 days from the date of this review. The Division of Drug Oncology Products recommended two additional doses, 250 mg and 750 mg once daily, for patients with baseline hepatic impairment and patients that develop hepatic toxicity while receiving Zytiga, respectively. DMEPA found the proposed name, Zytiga, acceptable in OSE Review 2010-2721, dated March 11, 2011.

## 2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name due to new product characteristics, DMEPA re-evaluates previous names of concern detailed in OSE Review 2010-2721, dated March 11, 2011, to determine if the new product characteristics could result in name confusion and render the proposed name unacceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of April 6, 2011.

The overall risk assessment is based on the findings of a Failure Mode and Effects Analysis (FMEA)[1] of the proposed proprietary name, which focuses on the avoidance of medication errors. FMEA was applied to determine if the proposed proprietary name could potentially be confused with the 31 names identified as potentially similar to Zytiga. This analysis determined that the name similarity between Zytiga and the identified names was unlikely to result in medication error for the reasons presented in Appendix A.

## 3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Zytiga, did not identify any vulnerabilities that would result in medication errors. Thus, DMEPA has no objection to the proprietary name, Zytiga, 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 Drug Oncology Products should notify DMEPA because the proprietary name must be re-reviewed prior to the new anticipated action date.

If you have further questions or need clarifications, please contact Sarah Simon, OSE project manager, at 301-796-5205.

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

## 4 REFERENCES


1. **OSE Review** Abdus-Samad, J. OSE 2010-2721: Proprietary Name Review for Zytiga. March 11, 2011.

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

   USAN Stems List contains all the recognized USAN stems.

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

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Jenloga (Clonidine Hydrochloride) | Look | 0.1 mg tablet | Take 1 to 6 tablets orally at bedtime<br>may be prescribed without a strength | **Orthographic differences:** Zytiga contains an additional downstroke letter (‘y’) and crosstroke letter (‘t) |
| Moxeza (Moxifloxacin Hydrochloride) | Look | 0.5 % ophthalmic solution | Instill 1 drop in the affected eye 3 times a day for 7 days | **Orthographic differences:** Zytiga contains an additional downstroke letter (‘y’).<br>**Dose:** 1 drop vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration**: ophthalmic solution vs. oral tablet |
| Mytrex A (Neomycin Sulfate and Triamcinolone Acetonide)) | Look | 3.5 mg base per g/0.1% cream, ointment | Apply to affected area as directed | **Orthographic differences:** Mytrex A contains an additional crosstroke letter (‘x’) at and a modifier ‘A’ at the end of the name<br>**Dose:** Apply vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical cream or ointment vs. oral tablets |
| Luxiq (Betamethasone Valerate) | Look | 0.12 % foam | Apply twice daily (once in the morning and once at night). | **Orthographic differences:** Zytiga contains an additional letter (lowercase ‘a’) after the downstroke letter ‘g’.<br>**Dose:** Apply vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical foam vs. oral tablets<br>**Frequency of Administration:** 2 times daily vs. once daily |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Lyrica (Pregabalin) | Look | 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg<br>Numerical similarity: 25 mg vs. 250 mg, 50 mg vs. 500 mg, 100 mg vs. 1,000 mg | Initial dose 75 mg tablet 2 times daily<br>Take 1 tablet orally 2 times daily (300 mg to 450 mg total daily dose) | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase letter 'g').<br>**Frequency of Administration:** 2 times daily vs. once daily<br>Maximum dose of Lyrica is 450 mg/day |
| Zelapar (Selegiline Hydrochloride) | Look | 1.25 mg orally dispersible tablet | Take 1 to 2 tablets orally once daily | **Orthographic differences:** Zytiga contains an additional downstroke letter (lowercase 'y').<br>**Dose:** 1.25 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg) |
| | | | | (b) (4) |

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| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
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| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Zyclara (Imiquimod) | Look | 3.75 % cream | Apply a thin film once daily before bedtime to the skin of the affected area (either the face or balding scalp). Leave on the skin for 8 hours, and then remove with mild soap and water.<br>*Both products can be prescribed without a strength* | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase 'g')<br>**Dose:** Apply a thin film vs. 1.25 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of Administration:** bedtime vs. once daily |
| Zydone (Hydrocodone Bitartrate and Acetaminophen ) | Look | 5 mg/400 mg tablet | Take 1 to 2 tablets every 4 hours to 6 hours. Max 8 tablets/day | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase 'g').<br>**Dose:** 5/400 mg vs. 1.25 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Frequency of Administration:** every 4 to 6 hours vs. once daily |
| Zyloprim (Allopurinol) | Look | 100 mg, 300 mg tablet<br>Numerical similarity: 100 mg vs. 1,000 mg | Take 1 to 3 tablets orally daily. Max 800 mg/daily. | **Orthographic differences:** Length of names (Zyloprim, 8 letters vs. Zytiga, 6 letters). The letters after the downstroke letters ('-rim' vs. '-a') toward the end of the name provide distinction. |
| Zyflo (Zileuton) | Look | 600 mg tablets | Take 1 tablet orally 4 times daily | **Dose:** 600 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Frequency of Administration:** 4 times daily vs. once daily |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Zyrtec (Cetirizine Hydrochloride) | Look | 5 mg, 10 mg tablets | Take 1 tablet orally daily | **Orthographic differences:** Zytiga contains an additional downstroke letter (lowercase 'g').<br>**Phonetic differences:** number of syllables (Zyr-tec, 2 vs. Zy-ti-ga, 3)<br>**Dose:** 5 mg or 10 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg) |
| Zytaze (Zinc Citrate and Phytase) | Look | 25 mg/ 1500 mg capsules | Take 2 capsules orally daily 4 days prior to and the day of botulinum toxin injections | Unapproved product that claims prescription only status.<br>Preliminary use data indicates use limited use of product. |
| Zytopic (Triamcinolone) | Look | 0.1 % cream | Apply to affected area 2 to 4 times daily<br>*Both products can be prescribed without a strength* | **Dose:** Apply a thin film vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of Administration:** 2 to 4 times daily vs. once daily |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Zetia (Ezetimibe) | Sound EPD | 10 mg tablet<br>Numerical similarity: 10 mg vs. 1000 mg | Take 1 tablet orally once daily | **Dose:** 10 mg (1 tablet) vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>Despite dose similarity (10 mg vs. 1,000 mg), these numbers are not phonetically similar. |
| [redacted] | | | | (b) (4) |
| Zyprexa (Olanzapine) | Look / Sound | 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg | Take 1 tablet orally once daily | **Orthographic differences:** Zytiga contains an additional upstroke and crosstroke letter (lowercase 'g').<br>**Phonetic differences:** the 2nd and 3rd syllables are phonetically different (prex-a vs. ti-ga)<br>**Dose:** 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg) |

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| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Betagan (Levobunolol Hydrochloride) | Look | 0.25 % ophthalmic solution<br><br>0.5 % ophthalmic solution | Instill 1 to 2 drops in the affected eye(s) twice daily<br><br>Instill 1 to 2 drops in the affected eye(s) 1 to 2 times daily | **Orthographic differences:** Zytiga contains an additional downstroke letter ('y').<br>**Dose**: 1 to 2 drops vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** ophthalmic solution vs. oral tablet<br>**Frequency of Administration:** 2 times daily vs. once daily |
| Cystagon (Cysteamine Bitartrate) | Look | 50 mg, 150 mg capsules | Take 50 mg to 500 mg orally 4 times daily | **Orthographic differences:** Length of name (Cystagon – 8 letters vs. Zytiga – 6 letters)<br>**Dose: 50 mg to 500 mg vs.** 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Frequency of Administration: 4 times daily vs. once daily** |
| [redacted] | | | | (b) (4) |
| Lutropin<br>Luveris (Lutropin Alfa) | Look | 75 units/vial | Inject 75 units to 225 units subcutaneously | **Orthographic differences: Length of name (Lutropin, 8 letters vs. Zytiga, 6 letters).**<br>**Dose: 75 units to 225 units vs.** 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration: subcutaneous injection vs. oral tablet** |

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| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| | | | | (b) (4) |
| Mytrex (Nystatin, Triamcinolone Acetonide) | Look | 100,000 units/ 0.1 % cream<br>100,000 units/ 0.1 % ointment | Apply sparingly as a thin film to the affected skin twice daily, morning and evening<br>Both products can be prescribed without a strength | **Orthographic differences:** Mytrex contains an additional crosstroke letter ('x') at the end of the name. Zytiga contains an additional downstroke letter (lowercase 'g').<br>**Dose: Apply thin film vs.** 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and frequency of administration:** topical cream or ointment vs. oral tablets |
| Vidaza (Azacitidine) | Look | 100 mg/vial for injection | Inject 75 mg/m2 to 100 mg/m2 daily for 7 days, every 4 weeks | **Orthographic differences: Zytiga contains an additional downstroke letter (lowercase 'y')**<br>**Dose: 120 mg to 190 mg (patient BSA 1.6 m2 to 1.9 m2) vs.** 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** subcutaneous injection vs. oral tablet |

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| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Vytone (Hydrocortisone and Iodoquinol) | Look | 1 %/1 % cream | Apply to the affected area as a thin film 3 to 4 times a day | **Orthographic differences:** Zytiga contains an additional downstroke letter (‘g’) toward the end of the name<br>**Dose:** Apply thin film vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of administration:** 3 to 4 times a day vs. once daily |
| Vytorin (Ezetimibe and Simvastatin) | Look | 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg | Take 1 tablet orally in the evening | **Orthographic differences: Zytiga contains an additional downstroke letter (‘g’) toward the end of the name**<br>**Dose:** 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg vs. 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg) |
| Cytoxan (Cyclophosphamide)<br>no longer marketed but generically available | Sound | 25 mg, 50 mg tablets | Take 1 mg/kg/day to 5 mg/kg/day (60 mg to 500 mg) orally once daily<br>(patient body weight 60 kg to 100 kg) | **Phonetic differences:** The last syllables are phonetically distinct (‘-xan’ vs. ‘-ga’).<br>Despite dose overlap, it is less likely chemotherapeutic agent, such as cytoxan, will be prescribed verbally. |
| | | 500 mg, 1 g, 2g for injection vials | Inject 10 mg/kg to 15 mg/kg (600 mg to 1500 mg) intravenously 7 to 10 days<br>*Achievable dose: 750 mg* | **Dose:** 600 mg to 1500 mg (patient body weight 60 kg to 100 kg) vs. 1, 2, or 4 tablets (250 mg, 500 mg, or 1000 mg)<br>**Dosage form and route of administration:** intravenous injection vs. oral tablet |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Sitagliptan Januvia (Sitagliptin Phosphate) | Sound | 25 mg, 50 mg, 100 mg<br>Numerical similarity: 25 mg, 50 mg, 100 mg vs. 250 mg, 500 mg, 1,000 mg | Take 1 tablet orally once daily | **Phonetic differences:** Sitagliptan has more syllables (Si-ta-glip-tan vs. Zy-ti-ga), with the last syllable ('-tan') being distinct.<br>Despite numerically similarity of doses, these doses are phonetically dissimilar. |
| Tyzeka (Telbivudine) | Sound (metathesis) | 600 mg tablet | Take 1 tablet orally daily | **Dose:** 600 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| | | 100 mg/5 mL oral solution | Take 30 mL (2 tablespoons) orally once daily | **Dose:** 30 mL (2 tablespoons)<br>**Dosage form:** oral solution vs. oral tablets |
| Cytogam (Cytomegalovirus Immune Globulin (Human)) | Look / Sound | 50 mg/mL | Inject 50 mg/kg to 150 mg/kg (3 g to 15g) intravenously at a rate of 15 mg/kg/hr to 60 mg/kg/hr | **Orthographic differences:** Length of name (Lutropin, 8 letters vs. Zytiga, 6 letters).<br>**Dose: 3g to 15 g vs.** 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)<br>**Dosage form and route of administration:** intravenous infusion vs. oral tablet |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
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| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1000 mg) orally daily (b) hour before or (b) hours after eating**<br>**Take 1, 2, or 3 tablets (250 mg, 500 mg, or 750 mg) orally daily (b) hour before or (b) hours after eating** (Hepatic Dose Modification**)** | **Dose: 1, 2, 3, or 4 tablets (250 mg, 500 mg, 750 mg, or 1000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily (b) hour before or (b) hours after eating** |
| Cytotec (Misoprostol) | Look / Sound | 100 mcg, 200 mcg tablet<br>Numerical similarity: 100 mcg vs. 1,000 mg | Take 1 tablet orally 4 times daily | **Orthographic differences:** Zytiga contains an additional downstroke (lowercase 'g') while in a similar position, Cytotec contains an upstroke and crosstroke letter (lowercase 't').<br>**Phonetic differences:** The last syllables are phonetically distinct ('-tec' vs. '-ga').<br>Despite numerical similarity of doses, these doses are phonetically dissimilar.<br>**Frequency of Administration:** 4 times daily vs. once daily |

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

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/s/

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JIBRIL ABDUS-SAMAD
04/13/2011

CAROL A HOLQUIST
04/13/2011

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

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| Date: | March 11, 2011 |
| Application Type/Number: | NDA 202379 |
| Through: | Todd Bridges, RPh, Team Leader<br>Carol Holquist, RPh, Director<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| From: | Jibril Abdus-Samad, PharmD, Safety Evaluator<br>Division of Medication Error Prevention and Analysis (DMEPA) |
| Subject: | Proprietary Name Review |
| Drug Name(s): | Zytiga (Abiraterone Acetate) Tablet, 250 mg |
| Applicant/Applicant: | Centocor Ortho Biotech, Inc |
| OSE RCM #: | 2010-2721 |

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## EXECUTIVE SUMMARY

This review summarizes DMEPA's evaluation of the proposed proprietary name, Zytiga for Abiraterone Acetate Capsules. Our evaluation determined the proposed proprietary name, Zytiga, is acceptable for this product. The proposed proprietary name must be re-evaluated 90 days prior to 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. The Applicant will be notified of our decision by letter.

## 1 BACKGROUND

### 1.1 INTRODUCTION

The Applicant, Centocor Ortho Biotech, Inc, requested an assessment of the proposed proprietary name in a submission dated December 20, 2010. The Division of Medication Error Prevention and Analysis (DMEPA) assesses a proposed proprietary name regarding its potential for name confusion with other proprietary or established drug names in the usual practice settings. Additionally, DMEPA considers the Division of Drug Marketing, Advertising and Communications' (DDMAC's) promotional assessment of the name.

### 1.2 PRODUCT INFORMATION

Zytiga is the proposed proprietary name for Abiraterone Acetate Tablets. Abiraterone Acetate is an inhibitor of CYP17 with a proposed indication of use with prednisone for the treatment of metastatic (b) (4) (b) (4) (b) (4) (castration resistant prostate cancer) in patients who have received prior chemotherapy containing a (b) (4) The recommend dose in adults is 1,000 mg (4 capsules) orally once daily that must not be taken with food. Zytiga should be taken at least two hours after eating and no food should be eaten for at least one hour after taking. Patients that develop hepatotoxicity during treatment with Zytiga may be given a reduced dose of 500 mg once daily. Zytiga will be available in 250 mg tablets and packaged into a bottle containing 120 tablets. Zytiga should be refrigerated at controlled room temperature, 77°F (25°C); excursions permitted to 59°F – 86°F (15-30°C).

## 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 and 2.2 identify information associated with the methodology for the proposed proprietary name, Zytiga.

## 2.1 SEARCH CRITERIA

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

To identify drug names that may look similar to Zytiga, the DMEPA safety evaluators 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), upstrokes (two, capital letter Z, lowercase t), down strokes (two, lowercase y', lowercase 'g'), cross strokes (one, lowercase t), and dotted letters (one, i). Additionally, several letters in Zytiga may be vulnerable to ambiguity when scripted (See Appendix B). As a result, the DMEPA staff also considers these alternate appearances when identifying drug names that may look similar to Zytiga.

When searching to identify potential names that may sound similar to Zytiga, the DMEPA safety evaluators search for names with similar number of syllables (three), stresses (ZY-ti-ga or zy-TI-ga), and placement of vowel and consonant sounds. The Applicant's intended pronunciation (zye ti' ga) was also taken into consideration, as it was included in the Proprietary Name Review Request. Moreover, 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 outpatient medication order, inpatient medication order and verbal prescription were communicated during the FDA prescription studies.

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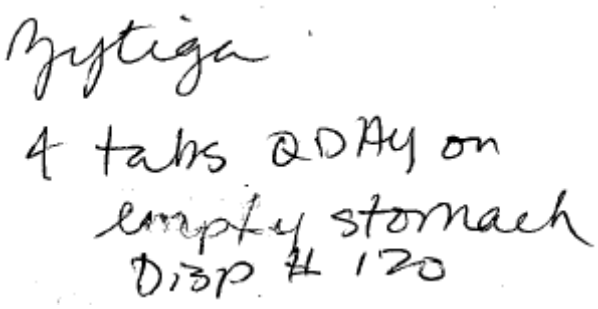
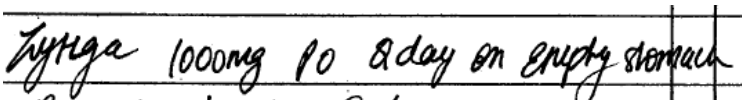
[1] Institute for Safe Medication Practices. Confused Drug name List (1996-2006). Available at http://www.ismp.org/Tools/confuseddrugnames.pdf

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

**Figure 1. Zytiga Prescription Study (conducted on February 7, 2011)**

| HANDWRITTEN REQUISITION MEDICATION ORDER | VERBAL PRESCRIPTION |
|---|---|
| Outpatient Medication Order:<br>  <br> | Zytiga 250 mg<br>4 po daily<br>Disp #120 |
| Inpatient Medication Order:<br>  <br> | |

## 3 RESULTS

The names identified from DMEPA's methods as potential sources for name confusion with Zytiga are listed below.

### 3.1 DATABASE AND INFORMATION SOURCES

Our searches of database and DMEPA's information sources yielded a total of 26 names as having some similarity to the name Zytiga.

Twenty-one of the names were thought to look like Zytiga. These include: Cyclogyl, (b) (4) Jenloga, (b) (4), Moxeza, Mytrex A, Luxiq, Lyrica, (b) (4), Zebeta, Zelapar, Zelrix, Ziagen, (b) (4) Zyclara, Zydone, Zyloprim, Zyflo, Zyrtec, Zytaze, and Zytopic. Two names, Zetia and (b) (4), were thought to sound like Zytiga. The three remaining names, (b) (4) Zyprexa, and Zytiga were thought to look and sound similar to Zytiga.

Additionally, DMEPA safety evaluators did not identify any United States Adopted Names stems in the proposed proprietary name, as of February 22, 2011.

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

### 3.2 CDER EXPERT PANEL DISCUSSION

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

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 48 practitioners responded to the prescription analysis study. Sixteen of the responses in the Outpatient Study were correct. All of the Inpatient Study responses were incorrect, with the most common misinterpretation being the letter 'r' for the letter 't'. Three responses (Lyrega, Lyriga, and Lyriga) look similar to Lyrica, a currently marketed product, which was also identified in the database search. Only five responses in the Verbal Study were correct. The most common misinterpretation was the lowercase letter 'e' for the lowercase letter 'i'.

### 3.4 COMMENTS FROM THE DIVISION OF DRUG ONCOLOGY (DDOP)

#### *3.4.1 Initial Phase of Review*

In response to a December 29, 2010, OSE e-mail, the Division of Drug Oncology Products (DDOP) discussed the name at the filing meeting and there were no objections.

#### *3.4.2 Midpoint of Review*

DMEPA notified DDOP via e-mail that we had no concerns with the proposed proprietary name, Zytiga, on March 7, 2011. Per e-mail correspondence from DDOP on March 11, 2011, they found the proposed proprietary name acceptable.

### 3.5 SAFETY EVALUATOR SEARCHES

Independent searches by the primary DMEPA safety evaluator resulted in the identification of 14 additional names thought to look or sound similar to Zytiga and represent a potential source of drug name confusion. Nine names (Betagan, Cystagon, (b) (4), Lutropin, (b) (4) Mytrex, Vidaza, Vytone, and Vytorin) were thought to look like Zytiga. Three names (Cytoxan, Sitagliptan, and Tyzeka) were thought to sound like Zytiga. The two remaining names (Cytogam and Cytotec) were thought to look and like Zytiga.

Thus, we identified in total, 40 names as having similarity to the proposed name.

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

## 4 DISCUSSION

This proposed name, Zytiga, was evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciplines involved with the review of this application was considered accordingly.

### 4.1 PROMOTIONAL ASSESSMENT

DDMAC had no concerns regarding the proposed name from a promotional perspective, and did not offer any additional comments relating to the proposed name. DMEPA and the DDOP concurred with the findings of DDMAC's promotional assessment of the proposed proprietary name.

### 4.2 SAFETY ASSESSMENT

DMEPA identified 40 names for their potential similarity to the proposed name, Zytiga. No other aspects of the name were determined to pose a different source for confusion with the name.

Nine of the 40 names were eliminated from further analysis for the reasons described in Appendices D.

Failure mode and effects analysis (FMEA) was applied to determine if the proposed proprietary name could potentially be confused with the remaining 31 names and lead to medication errors. This analysis determined that the name similarity between Zytiga and all of the 31 identified names was unlikely to result in medication error for the reasons presented in Appendix E.

## 5 CONCLUSIONS AND RECOMMENDATIONS

We have completed our review of the proposed proprietary name, Zytiga, and it is not promotional nor is it vulnerable to name confusion that could lead to medication errors. Thus, the Division of Medication Error Prevention and Analysis has no objections to the use of the proprietary name, Zytiga, at this time. The Applicant will be notified of this determination via letter.

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.

If you have further questions or need clarifications, please contact Sarah Simon, project manager, at 301-796-5205.

## 5.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name will be re-reviewed 90 days before 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 as stated in your December 20, 2010, submission are altered, 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 Applicant 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/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

USAN Stems List contains all the recognized USAN stems.

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

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

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

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

***16. Medical Abbreviations Book***

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

## APPENDICES

### Appendix A:

FDA's Proprietary Name Risk Assessment considers the 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, NDA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

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

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

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

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

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

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.

[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<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name<br>Upstrokes<br>Down strokes<br>Cross-strokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

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

### 1. Database and Information Sources

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

### 2. CDER Expert Panel Discussion

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

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

### 3. FDA Prescription Analysis Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of the 123 participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants send their interpretations of the orders via e-mail to DMEPA.

### 4. Comments from the OND review Division or Generic drugs

DMEPA requests the Office of New Drugs (OND) or Office of Generic Drugs (OGD) Regulatory Division responsible for the application for their comments or concerns with the proposed proprietary name and any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with DDMAC's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND or OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to concur/not concur with DMEPA's final decision.

### 5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

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

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

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

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

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

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.

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), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names 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).

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.

**Appendix B:** Potential orthographic or phonetic misinterpretation of the letters in the name Zytiga

| **Letters in Name, Zytiga** | **Scripted may appear as** | **Spoken may be interpreted as** |
|---|---|---|
| Capital 'Z' | B, F, L, M, T | cy, s, x |
| lowercase 'z' | m, | |
| lowercase 'y' | g, j, q | any vowel |
| lowercase 't' | f, l, x | k |
| lowercase 'i' | e | any vowel |
| lowercase 'g' | q, y | ck, k |
| lowercase 'a' | ci, ce, o, u | any vowel |

**Appendix C:** FDA Prescription Study Responses (December 2, 2010)

| INPATIENT | VOICE | OUTPATIENT |
|---|---|---|
| Lyrega | Cytega | Zijtiga |
| Lyriga | Cytega | Zytiga |
| Lyriga | Zitega | Zytiga |
| Trysiga | Zitega | Zytiga |
| Zyliga | Zytega | Zytiga |
| Zynga | Zytega | Zytiga |
| Zynga | Zytega | Zytiga |
| Zyrega | Zytica | Zytiga |
| Zyrga | Zytiga | Zytiga |
| Zyriga | Zytiga | Zytiga |
| Zyriga | Zytiga | Zytiga |
| Zyriga | Zytiga | Zytiga |
| Zyriga | zatiga | Zytiga |
| Zysiga | zitiga | zytiga |
| Zysiga | zytega | zytiga |
| zysiga? 1000mg po qday on empty stomach | zytiga | zytiza |

**Appendix D:** Proprietary names not considered further for reasons described

| Proprietary Name | Similarity to Zytiga | Comments |
|---|---|---|
| Cyclogyl (Cyclopentolate Hydrochloride) | Look | Lacks significant orthographic or phonetic similarities |
| (b) (4) | | |
| (b) (4) | | |
| Zebeta (Bisoprolol Fumarate) | Look | Lacks significant orthographic or phonetic similarities |
| (b) (4) | | |
| Ziagen (Abacavir Sulfate) | Look | Lacks significant orthographic or phonetic similarities |
| (b) (4) | | |
| Zytiga | Look and Sound | trademark licensed to Johnson and Johnson, whom the Applicant is subsidiary. |

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

**Appendix E:** Proprietary names not considered further for reasons described

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** (4 (4 |
| Jenloga (Clonidine Hydrochloride) | Look | 0.1 mg tablet | Take 1 to 6 tablets orally at bedtime<br>may be prescribed without a strength | **Orthographic differences:** Zytiga contains an additional downstroke letter ('y') and crosstroke letter ('t) |
| Moxeza (Moxifloxacin Hydrochloride) | Look | 0.5 % ophthalmic solution | Instill 1 drop in the affected eye 3 times a day for 7 days | **Orthographic differences:** Zytiga contains an additional downstroke letter ('y').<br>**Dose:** 1 drop vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration**: ophthalmic solution vs. oral tablet |
| Mytrex A (Neomycin Sulfate and Triamcinolone Acetonide)) | Look | 3.5 mg base per g/0.1% cream, ointment | Apply to affected area as directed | **Orthographic differences:** Mytrex A contains an additional crosstroke letter ('x') at and a modifier 'A' at the end of the name<br>**Dose:** Apply vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical cream or ointment vs. oral tablets |
| Luxiq (Betamethasone Valerate) | Look | 0.12 % foam | Apply twice daily (once in the morning and once at night). | **Orthographic differences:** Zytiga contains an additional letter (lowercase 'a') after the downstroke letter 'g'.<br>**Dose:** Apply vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical foam vs. oral tablets<br>**Frequency of Administration:** 2 times daily vs. once daily |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Lyrica (Pregabalin) | Look | 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, 300 mg<br>Numerical similarity: 50 mg vs. 500 mg, 100 mg vs. 1,000 mg | Initial dose 75 mg tablet 2 times daily<br>Take 1 tablet orally 2 times daily (300 mg to 450 mg total daily dose) | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase letter 'g').<br>**Frequency of Administration:** 2 times daily vs. once daily<br>Maximum dose of Lyrica is 450 mg/day |
| Zelapar (Selegiline Hydrochloride) | Look | 1.25 mg orally dispersible tablet | Take 1 to 2 tablets orally once daily | **Orthographic differences:** Zytiga contains an additional downstroke letter (lowercase 'y').<br>**Dose:** 1.25 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| [redacted] | | | | (b) (4) |

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| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Zyclara (Imiquimod) | Look | 3.75 % cream | Apply a thin film once daily before bedtime to the skin of the affected area (either the face or balding scalp). Leave on the skin for 8 hours, then remove with mild soap and water.<br>*Both products can be prescribed without a strength* | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase 'g')<br>**Dose:** Apply a thin film vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of Administration:** bedtime vs. once daily |
| Zydone (Hydrocodone Bitartrate and Acetaminophen ) | Look | 5 mg/400 mg tablet | Take 1 to 2 tablets every 4 hours to 6 hours. Max 8 tablets/day | **Orthographic differences:** Zytiga contains an additional crosstroke letter (lowercase 't') and downstroke letter (lowercase 'g').<br>**Dose:** 5/400 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Frequency of Administration:** every 4 to 6 hours vs. once daily |
| Zyloprim (Allopurinol) | Look | 100 mg, 300 mg tablet<br>Numerical similarity: 100 mg vs. 1,000 mg | Take 1 to 3 tablets orally daily. Max 800 mg/daily. | **Orthographic differences:** Length of names (Zyloprim, 8 letters vs. Zytiga, 6 letters). The letters after the downstroke letters ('-rim' vs. '-a') toward the end of the name provide distinction. |
| Zyflo (Zileuton) | Look | 600 mg tablets | Take 1 tablet orally 4 times daily | **Dose:** 600 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Frequency of Administration:** 4 times daily vs. once daily |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Zyrtec (Cetirizine Hydrochloride) | Look | 5 mg, 10 mg tablets | Take 1 tablet orally daily | **Orthographic differences:** Zytiga contains an additional downstroke letter (lowercase 'g').<br>**Phonetic differences:** number of syllables (Zyr-tec, 2 vs. Zy-ti-ga, 3)<br>**Dose:** 5 mg or 10 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| Zytaze (Zinc Citrate and Phytase) | Look | 25 mg/ 1500 mg capsules | Take 2 capsules orally daily 4 days prior to and the day of botulinum toxin injections | Unapproved product that claims prescription only status.<br>Preliminary use data indicates use limited use of product. |
| Zytopic (Triamcinolone) | Look | 0.1 % cream | Apply to affected area 2 to 4 times daily<br>*Both products can be prescribed without a strength* | **Dose:** Apply a thin film vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of Administration:** 2 to 4 times daily vs. once daily |
| Zetia (Ezetimibe) | Sound EPD | 10 mg tablet | Take 1 tablet orally once daily | **Dose:** 10 mg (1 tablet) vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>Despite dose similarity (10 mg vs. 1,000 mg), these numbers are not phonetically similar. |
| (b) (4) | | | | |

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| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Zyprexa (Olanzapine) | Look / Sound | 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg | Take 1 tablet orally once daily | **Orthographic differences:** Zytiga contains an additional upstroke and crosstroke letter (lowercase 'g').<br>**Phonetic differences:** number of syllables (Zyr-tec, 2 vs. Zy-ti-ga, 3)<br>**Dose:** 5 mg or 10 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| Betagan (Levobunolol Hydrochloride) | Look | 0.25 % ophthalmic solution<br><br>0.5 % ophthalmic solution | Instill 1 to 2 drops in the affected eye(s) twice daily<br><br>Instill 1 to 2 drops in the affected eye(s) 1 to 2 times daily | **Orthographic differences:** Zytiga contains an additional downstroke letter ('y').<br>**Dose:** 1 to 2 drops vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration**: ophthalmic solution vs. oral tablet<br>**Frequency of Administration:** 2 times daily vs. once daily |
| Cystagon (Cysteamine Bitartrate) | Look | 50 mg, 150 mg capsules | Take 50 mg to 500 mg orally 4 times daily | **Orthographic differences:** Length of name (Cystagon – 8 letters vs. Zytiga – 6 letters)<br>**Dose:** 50 mg to 500 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Frequency of Administration:** 4 times daily vs. once daily |

(b) (4)

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| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Lutropin<br>Luveris (Lutropin Alfa) | Look | 75 units/vial | Inject 75 units to 225 units subcutaneously | **Orthographic differences:** Length of name (Lutropin, 8 letters vs. Zytiga, 6 letters).<br>**Dose:** 75 units to 225 units vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration**: subcutaneous injection vs. oral tablet |
| [redacted] | | | | (b) (4) |
| Mytrex (Nystatin, Triamcinolone Acetonide) | Look | 100,000 units/ 0.1 % cream<br>100,000 units/ 0.1 % ointment | Apply sparingly as a thin film to the affected skin twice daily, morning and evening<br>*Both products can be prescribed without a strength* | **Orthographic differences:** Mytrex contains an additional crosstroke letter ('x') at the end of the name. Zytiga contains an additional downstroke letter (lowercase 'g').<br>**Dose:** Apply thin film vs. 2 tablets (500 mg), tablets (1,000 mg)<br>**Dosage form and frequency of administration:** topical cream or ointment vs. oral tablets |
| Vidaza (Azacitidine) | Look | 100 mg/vial for injection | Inject 75 mg/m$^2$ to 100 mg/m$^2$ daily for 7 days, every 4 weeks | **Orthographic differences:** Zytiga contains an additional downstroke letter (lowercase 'y')<br>**Dose:** 120 mg to 190 mg (patient BSA 1.6 m$^2$ to 1.9 m$^2$) vs. 500 mg, 1,000 mg (2 or 4 tablets)<br>**Dosage form and route of administration**: subcutaneous injection vs. oral tablet |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take 2 tablets (500 mg) orally q daily (b) hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Vytone (Hydrocortisone and Iodoquinol) | Look | 1 %/1 % cream | Apply to the affected area as a thin film 3 to 4 times a day | **Orthographic differences:** Zytiga contains an additional downstroke letter ('g') toward the end of the name<br>**Dose:** Apply thin film vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration:** topical cream vs. oral tablets<br>**Frequency of administration:** 3 to 4 times a day vs. once daily |
| Vytorin (Ezetimibe and Simvastatin) | Look | 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg | Take 1 tablet orally in the evening | **Orthographic differences:** Zytiga contains an additional downstroke letter ('g') toward the end of the name<br>**Dose:** 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| Cytoxan (Cyclophosphamide)<br>*no longer marketed but generically available* | Sound | 25 mg, 50 mg tablets | Take 1 mg/kg/day to 5 mg/kg/day (60 mg to 500 mg) orally once daily<br>(patient body weight 60 kg to 100 kg) | **Phonetic differences:** The last syllables are phonetically distinct ('-xan' vs. '-ga').<br>Despite dose overlap, it is less likely chemotherapeutic agent, such as cytoxan, will be prescribed verbally. |
| | | 500 mg, 1 g, 2g for injection vials | Inject 10 mg/kg to 15 mg/kg **(**600 mg to 1500 mg) intravenously 7 to 10 days | **Dose:** 600 mg to 1500 mg (patient body weight 60 kg to 100 kg)<br>**Dosage form and route of administration**: intravenous injection vs. oral tablet |
| Sitagliptan Januvia (Sitagliptin Phosphate) | Sound | 25 mg, 50 mg, 100 mg<br>Numerical similarity: 50 mg, 100 mg vs. 500 mg, 1,000 mg | Take 1 tablet orally once daily | **Phonetic differences:** Sitagliptan has more syllables (Si-ta-glip-tan vs. Zy-ti-ga), with the last syllable ('-tan') being distinct.<br>Despite numerically similarity of doses, these doses are phonetically dissimilar. |

| Product name with potential for confusion | Similarity to Zytiga | Strength, Dosage Form | Usual Dose | Differing product characteristics that minimize the risk of medication error |
|---|---|---|---|---|
| **Zytiga (abiraterone acetate)** | | **250 mg capsules** | **Take 4 tablets (1,000 mg) orally qdaily (b) hour before or (b) hours after eating**<br>**Take (b) tablets (500 mg) orally q daily 1 hour before or (b) hours after eating** (Hepatic Dose Adjustment**)** | **Dose: 2 tablets (500 mg), 4 tablets (1,000 mg)**<br>**Dosage Form: tablet**<br>**Route of Administration: oral**<br>**Frequency of Administration: once daily on (b) hour before or (b) hours after eating** |
| Tyzeka (Telbivudine) | Sound (metathesis) | 600 mg tablet | Take 1 tablet orally daily | **Dose:** 600 mg vs. 2 tablets (500 mg), 4 tablets (1,000 mg) |
| | | 100 mg/5 mL oral solution | Take 30 mL (2 tablespoons) orally once daily | **Dose:** 30 mL (2 tablespoons)<br>**Dosage form:** oral solution vs. oral tablets |
| Cytogam (Cytomegalovirus Immune Globulin (Human)) | Look / Sound | 50 mg/mL | Inject 50 mg/kg to 150 mg/kg (3 g to 15g) intravenously at a rate of 15 mg/kg/hr to 60 mg/kg/hr | **Orthographic differences:** Length of name (Lutropin, 8 letters vs. Zytiga, 6 letters).<br>**Dose:** 3g to 15 g vs. 2 tablets (500 mg), 4 tablets (1,000 mg)<br>**Dosage form and route of administration**: intravenous infusion vs. oral tablet |
| Cytotec (Misoprostol) | Look / Sound | 100 mcg, 200 mcg tablet<br>Numerical similarity: 100 mcg vs. 1,000 mg | Take 1 tablet orally 4 times daily | **Orthographic differences:** Zytiga contains an additional downstroke (lowercase 'g') while in a similar position, Cytotec contains an upstroke and crosstroke letter (lowercase 't').<br>**Phonetic differences:** The last syllables are phonetically distinct ('-tec' vs. '-ga').<br>Despite numerical similarity of doses, these doses are phonetically dissimilar.<br>**Frequency of Administration:** 4 times daily vs. once daily |

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

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/s/

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JIBRIL ABDUS-SAMAD
03/11/2011

TODD D BRIDGES
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CAROL A HOLQUIST
03/14/2011