CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-835/S022

21-621/S005

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; White Oak 22; Mail Stop 4447)

DATE RECEIVED: Feb. 16, 2007 **DATE OF DOCUMENT:** Jan. 15, 2007	**DESIRED COMPLETION DATE:** Aug. 15, 2007 **PDUFA DATE:** Nov. 16, 2007	**OSE REVIEW #:** 2007-400, 2007-402, 2007-403, 2007-404, 2007-405, 2007-406, 2007-407

TO: Andrea Leonard-Segal, MD
Director, Division of Nonprescription Clinical Evaluation
HFD-560

THROUGH: Kellie Taylor, PharmD, Team Leader
Denise Toyer, PharmD, Deputy Director
Carol Holquist, RPh, Director
Division of Medication Errors and Technical Support, HFD-420

FROM: Felicia Duffy, RN, Safety Evaluator
Division of Medication Errors and Technical Support, HFD-420

PRODUCT NAME:	**SPONSOR:**
Children's Zyrtec Hives Relief (Cetirizine HCl Syrup); 1 mg/mL NDA 22-155 **Children's Zyrtec Allergy** (Cetirizine HCl Chewable Tablets); 5 mg and 10 mg **Children's Zyrtec Hives Relief** (Cetirizine HCl Chewable Tablets); 5 mg and 10 mg NDA 21-621 **Zyrtec Allergy** (Cetirizine HCl Tablets); 5 mg and 10 mg **Zyrtec Hives Relief** (Cetirizine HCl Tablets); 5 mg NDA 19-835 **Zyrtec-D Allergy & Congestion** (Cetirizine HCl and Pseudoephedrine HCl Tablets); 5 mg/120 mg NDA 21-150	Pfizer

RECOMMENDATIONS:

1. DMETS has no objections to the use of the proprietary names, Children's Zyrtec Allergy, Zyrtec Allergy, and Zyrtec-D Allergy & Congestion. 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 does not recommend the use of the proprietary names, Children's Zyrtec Hives Relief and Zyrtec Hives Relief.

3. DMETS recommends implementation of the label and labeling recommendations outlined in section III of this review in order to minimize potential errors with the use of this product.

4. DDMAC dose not provide comments on the promotional aspect of over-the-counter drug products. The Federal Trade Commission (FTC) regulates the promotional aspects of these products.

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 forwarded to the sponsor pertaining to this review. If you have further questions or need clarifications, please contact Cherye Milburn, Project Manager, at 301-796-2084.

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

PROPRIETARY NAME, LABEL AND LABELING REVIEW

DATE OF REVIEW: May 15, 2007

NDA #s: 19-835, 21-150, 21-621, and 22-155

NAME OF DRUG: **Children's Zyrtec Hives Relief** (Cetirizine HCl Syrup); 1 mg/mL
Children's Zyrtec Hives Relief (Cetirizine HCl Chewable Tablets); 5 mg, 10 mg
Children's Zyrtec Allergy (Cetirizine HCl Chewable Tablets); 5 mg and 10 mg
Zyrtec Allergy (Cetirizine HCl Tablets); 5 mg and 10 mg
Zyrtec Hives Relief (Cetirizine HCl Tablets); 5 mg
Zyrtec-D Allergy & Congestion (Cetirizine HCl and Pseudoephedrine HCl Tablets); 5 mg/120 mg

NDA SPONSOR: Pfizer

I. INTRODUCTION

This consult was written in response to a request from the Division of Nonprescription Clinical Evaluation, for an assessment of the proprietary names "Children's Zyrtec Hives Relief", "Children's Zyrtec Allergy", "Zyrtec Allergy", "Zyrtec Hives Relief", and "Zyrtec-D Allergy & Congestion" regarding potential name confusion with other proprietary or established drug names. Carton, container and insert labeling were provided for review and comment.

PRODUCT INFORMATION

The sponsor proposes to switch the prescription Zyrtec from Prescription to OTC with these NDA submissions.
Zyrtec (cetirizine hydrochloride) is currently a prescription drug product available in multiple dosage forms:

Product Name	Dosage Form	Date Approved	Strength
Zyrtec	Syrup	September 1996	5 mg/5 mL
Zyrtec-D	Extended-release Tablet	August 2001	5 mg/120 mg
Zyrtec	Chewable Tablet	March 2004	5 mg and 10 mg
Zyrtec	Tablet	December 2005	5 mg and 10 mg

Below is a narrative description of the proposed OTC Zyrtec products, and the table on page 3 outlines the characteristics of the proposed products.

Zyrtec Hives Relief and Children's Zyrtec Hives Relief contain the active ingredient cetirizine HCl. Both products are indicated for the relief of itching due to hives (urticaria). Zyrtec Hives Relief will be available as 5 mg tablets, and Children's Zyrtec Hives Relief will be available as 5 mg and 10 mg chewable tablets and as a 1 mg/mL syrup. Zyrtec Allergy and Children's Zyrtec Allergy also contain the active ingredient cetirizine HCl. Both drug products are indicated for the temporary relief of symptoms due to hay fever, [redacted] or other upper respiratory allergies. Zyrtec Allergy will be available in 5 mg and 10 mg tablets, and Children's Zyrtec Allergy will be available in 5 mg and 10 mg chewable tablets.

II. RISK ASSESSMENT

The medication error staff of DMETS conducted a search of the internet, several standard published drug product reference texts[1,2] as Children's Zyrtec Hives Relief, Children's Zyrtec Allergy, Zyrtec Hives Relief, Zyrtec Allergy, and Zyrtec-D Allergy & Congestion as well as several FDA databases[3,4] for existing drug names which sound-alike or look-alike 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[5]. The Saegis[6] 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. In addition, DMETS conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Following completion of these initial steps, an overall risk assessment is conducted that does not evaluate the name alone. The assessment considers the findings from above and more importantly, integrates post-marketing experience in assessing the risk of name confusion, product label/labeling, and product packaging. Because it is the product that is inserted into the complex and unpredictable U.S. healthcare environment, all product characteristics of a drug must be considered in the overall safety evaluator risk assessment.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary names, Children's Zyrtec Hives Relief, Children's Zyrtec Allergy, Zyrtec Hives Relief, Zyrtec Allergy, and Zyrtec-D Allergy & Congestion. 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 does not provide comments on the promotional aspect of over-the-counter drug products. The Federal Trade Commission (FTC) regulates the promotional aspects of these products.

2. The Expert Panel identified the following names as potentially having confusion with:

   - Zyrtec Allergy: Zyrtec, Zyprexa, Zyrtec-D 12 Hour, Zantac, Zylet, Allergy Tablets, Tavist Allergy, Children's Zyrtec Allergy, and Zyrtec-D Allergy & Congestion.

   - Children's Zyrtec Allergy: Zyrtec, Zyprexa, Zyrtec-12 Hour, Zantac, Benadryl Children's Allergy, Equate Children's Allergy, Children's Advil Allergy Sinus, Zylet, and Zyrtec Allergy.

---

[1] MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.
[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, MO.
[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.
[4] Phonetic and Orthographic Computer Analysis (POCA)
[5] WWW location http://www.uspto.gov/tmdb/index.html.
[6] Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at www.thomson-thomson.com

- Zyrtec Hives Relief: Zyrtec, Zyprexa, Zantac, Zylet, Claritin Hives Relief, Zyrtec-D 12 Hour, and Children's Zyrtec Hives Relief.

- Children's Zyrtec Hives Relief: Zantac, Zyprexa, Zyrtec, Zyrtec-D 12 Hour, Claritin Hives Relief, Zylet, and Zyrtec Hives Relief.

- Zyrtec-D Allergy & Congestion: Zantac, Zyprexa, Zylet, Zyrtec-D 12 Hour, and Zyrtec Allergy.

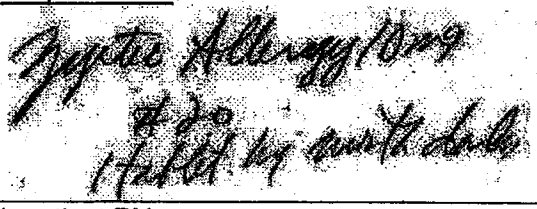
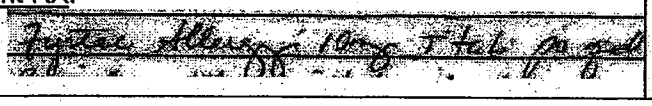
3. The Expert Panel recommended searching the FDA Adverse Event Reporting System (AERS) and the Drug Quality Reporting System (DQRS) to search for medication errors with the Zyrtec product line since Zyrtec is already approved as a prescription product.

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary names (Zyrtec Allergy, Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion) to determine the degree of confusion of Zyrtec Allergy, Zyrtec Hives Relief, and Zyrtec-D Allergy and Congestion 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. Each study employed a total of 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Zyrtec Allergy, Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion (see below and page 6). These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were 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 sent their interpretations of the orders via e-mail to the medication error staff. Prescription studies were not conducted for Children's Zyrtec Allergy and Children's Zyrtec Hives Relief due to an oversight. However, DMETS believes the results for Zyrtec Allergy and Zyrtec Hives Relief may be applicable to the Children's Zyrtec products.

Zyrtec Allergy

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: 	Zyrtec Allergy 10 mg Sig: Take 1 tablet by mouth once daily Dispense: #20
Inpatient RX: 	

Zyrtec Hives Relief

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Zyrtec Hives Relief 5mg #30 1 or 2 tablet per day	Zyrtec Hives Relief 5 mg Sig: Take 1-2 tablets by mouth once daily. Dispense: #30
Inpatient RX: Zyrtec Hives Relief 5mg 1-2 po qd	

Zyrtec-D Allergy & Congestion

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: Zyrtec-D Allergy & Congestion #60 1 tablet by mouth every 12 hours	Zyrtec-D Allergy & Congestion Sig: Take 1 tablet by mouth every 12 hours. Dispense: #60
Inpatient RX: ① Zyrtec-D Allergy & Congestion 1 po q12	

2. Results for Zyrtec Allergy, Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion prescription studies:

   None of the responses in the interpretations of the proposed names overlap, sounds similar, or looks similar to any currently marketed U.S. product. See Appendices A, B, and C for the complete listing of interpretations from the verbal and written studies.

C. ADVERSE EVENT REPORTING SYSTEM (AERS) and DRUG QUALITY REPORTING SYSTEM (DQRS)

DMETS has previously evaluated post-marketing errors of name confusion with Zyrtec. The most recent review was completed on April 18, 2005 (OSE review #01-0233-2). Post-marketing surveillance of the proprietary name Zyrtec has shown name confusion errors occur primarily between Zyrtec and Zantac, and Zyrtec and Zyprexa. The remaining name confusion errors occurred with Zyrtec and other miscellaneous products. A summary of the Zyrtec medication error narratives is located in Appendix D.

DMETS searched the FDA Adverse Event Reporting System (AERS) and the Drug Quality Reporting System (DQRS) databases to determine the number of medication error cases reported with Zyrtec since the last post-marketing review. DMETS searched for additional medication errors from January 1, 2005 to July 18, 2007.

The MedDRA High Level Term (HLT), "Medication Errors NEC", and the Preferred Terms (PT), "Overdose", "Accidental Overdose", "Wrong Drug Administered", "Intercepted Drug Administration", "Drug Administration Error", and "Pharmaceutical Product Complaint", and tradename and verbatim

"Zyrtec%" were used to perform the searches. In addition, the Drug Quality Reporting System (DQRS) database was searched for similar reports with "Zyrtec". This combined search strategy retrieved 30 new cases relevant to the labels and labeling of Zyrtec which brings the total to 184. The errors are categorized as follows:

Zyrtec and Zyprexa (n= 79)

DMETS received 11 medication error cases in addition to the 68 cases reported in the April 18, 2005 DMETS review, bringing the total number of cases to 79.

Zyrtec and Zantac (n=71)

Since the follow-up consult on April 18, 2005 which reported a total of 57 cases, DMETS received 14 additional cases of medication errors concerning Zyrtec and Zantac, bringing the total number of cases to 71.

Zyrtec and Miscellaneous Products (n=5)

In addition to Zyrtec/Zyprexa and Zyrtec/Zantac confusion, a few other name confusion pairs have been identified since our last review during routing post-marketing medication error surveillance. Three (n=3) cases involving Zyrtec and Zetia, one (n=1) case with Zyrtec and Zyrtec-D, and one (n=1) case with Zyrtec and Norvasc.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proposed Zyrtec OTC product line, DMETS identified general safety concerns relating to the introduction of the Zyrtec product line.

Zyrtec is currently available by prescription only, and it is available in four different dosage forms: syrup, chewable tablets, tablets, and extended-release tablets. The only way to differentiate between the currently marketed Zyrtec products is to specify the dosage form. The OTC Zyrtec product line will contain specific descriptors such as: Zyrtec Allergy, Zyrtec Hives Relief, Children's Zyrtec Allergy, Children's Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion.

DMETS anticipates that practitioners and consumers may experience confusion between the different OTC Zyrtec products because the prescription Zyrtec products did not contain descriptors. Once the Zyrtec OTC product line is launched, initially, consumers may not know which Zyrtec product to choose because there will be several Zyrtec OTC products to choose from. Specifically, consumers will need to choose a Zyrtec product based on its indication of use (allergy, hives relief, or allergy and congestion). Additionally, the OTC products will be specific for adults or pediatric consumers. Thus, DMETS recommends that educational measures be taken to emphasize the difference in the pediatric and adult formulations and dosing recommendations for the different age groups. This plan should be executed before and after product launch.

Additionally, because all of the OTC Zyrtec products contain the same active ingredient, the potential exists for consumers to overdose on cetirizine hydrochloride if they take more than one OTC Zyrtec product concurrently (e.g., Zyrtec Hives Relief and Zyrtec Allergy). Therefore, it will be important for the educational measures to inform consumers not to use more than one OTC Zyrtec product simultaneously.

DMETS has also identified safety concerns specifically relating to the product line nomenclature, which are discussed in detail below.

1. Product line nomenclature

   DMETS has concerns relating to the nomenclature of the OTC Zyrtec products, including the potential for confusion within the product line, name confusion with other marketed drug products, and the misleading nature of the "Hives Relief" descriptor.

   The Expert Panel identified the following names that may be potentially confused with the proposed Zyrtec product line tradenames:

   - Zyrtec Allergy: Zyrtec, Zyprexa, Zyrtec-D 12 Hour, Zantac, Zylet, Allergy Tablets, Tavist Allergy, Children's Zyrtec Allergy, and Zyrtec-D Allergy & Congestion.

   - Children's Zyrtec Allergy: Zyrtec, Zyprexa, Zyrtec-12 Hour, Zantac, Benadryl Children's Allergy, Equate Children's Allergy, Children's Advil Allergy Sinus, Zylet, and Zyrtec Allergy.

   - Zyrtec Hives Relief: Zyrtec, Zyprexa, Zantac, Zylet, Claritin Hives Relief, Zyrtec-D 12 Hour, and Children's Zyrtec Hives Relief.

   - Children's Zyrtec Hives Relief: Zantac, Zyprexa, Zyrtec, Zyrtec-D 12 Hour, Claritin Hives Relief, Zylet, and Zyrtec Hives Relief.

   - Zyrtec-D Allergy & Congestion: Zantac, Zyprexa, Zylet, Zyrtec-D 12 Hour, and Zyrtec Allergy.

   Upon preliminary analysis, the names, Zylet, Allergy Tablets, Tavist Allergy, Benadryl Children's Allergy, Equate Children's Allergy, Children's Advil Allergy Sinus, and Claritin Hives Relief were not considered further due to the lack of look-alike and/or sound-alike similarity to Zyrtec Allergy, Children's Zyrtec Allergy, Zyrtec Hives Relief, Children's Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion; in addition to differentiating product characteristics such as product strength, indication of use, active ingredient, dose, dosage form, frequency of administration, and route of administration. However, Zyprexa, Zantac and Zyrtec product line names are discussed in further detail below.

   The names reviewed in detail are listed in Table 1 on page 9.

Table 1: Potential Sound-Alike and Look-Alike Names Identified by DMETS Expert Panel for the Zyrtec product line

Product Line	Product Name	Established name; Dosage form(s)	Usual adult dose
Proposed Zyrtec OTC products	Zyrtec Allergy	Cetirizine HCl Tablets: 5 mg and 10 mg	Adults and children >6 yrs: *5 mg tabs*: Take 1-2 tablets by mouth once daily. Maximum of 10 mg in 24 hours. *10 mg tablets*: Take 1 tablet by mouth once daily. Maximum of 10 mg in 24 hours.
	Zyrtec Hives Relief	Cetirizine HCl Tablets: 5 mg and 10 mg	**5 mg tablets** Adults and children >6yrs: 1-2 tabs by mouth once daily. Maximum of 2 tabs in 24 hours. **10 mg tablets** Adults and children >6yrs: 1 tablet by mouth once daily. Max 1 tab in 24 hours.
	Children's Zyrtec Allergy	Cetirizine HCl Chewable tablets: 5 mg Syrup: 1 mg/mL	Chewable tablets: Adults and children >6yrs: 1-2 tablets by mouth once daily. Maximum of 2 tablets in 24 hours. Children 2-6 yrs: 1 tablet by mouth once daily. Syrup: Adults and children >6yrs: 1-2 teaspoons once daily. Maximum of 2 tsp in 24 hours. Children 2-6 yrs: ½ - 1 tsp once daily. Maximum of 1 tsp in 24 hours.
	Children's Zyrtec Hives Relief	Cetirizine HCl Chewable Tablets: 5 mg and 10 mg Syrup: 1 mg/mL	Chewable tablets: Adults and children >6 yrs: *5 mg*: 1-2 tablets by mouth once daily. Maximum of 2 tabs in 24 hours. *10 mg*: 1 tablet by mouth once daily. Maximum of 1 tab in 24 hours. Syrup: Adults and children >6 yrs: 1-2 teaspoons once daily. Maximum of 2 teaspoons in 24 hours.
	Zyrtec D Allergy & Congestion	Cetirizine HCl and Pseudoephedrine Extended-release tablets 5 mg/120 mg	Take 1 tablet by mouth every 12 hours. Maximum of 2 tablets in 24 hours.
Zantac RX product line	Zantac (Rx) Zantac 25 (Rx) Zantac 150 (Rx) Zantac 300 (Rx)	Ranitidine HCl Tablets: 150 mg and 300 mg Effervescent tablet: 25 mg and 150 mg Effervescent granules: 150 mg Injection: 1 mg/mL, 25 mg/mL Syrup: 15 mg/mL	Rx: oral dosage forms Adults: 150 mg by mouth once daily, twice daily or 4 times daily. Children: 2-4 mg/kg by mouth once or twice daily. Injection: Adults: 50 mg IM or IV every 6-8 hours. Children: 2-4 mg/kg divided and given every 6 -8 hours up to a maximum of 50 mg every 8 hours.
Zantac OTC product line	Zantac 75 (OTC) Zantac 150 (OTC)	Ranitidine HCl Tablets: 75 mg and 150 mg	OTC tablets: 1 tablet by mouth, can be used up to twice daily.
	Zyprexa	Olanzapine Tablet: 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg Injection: 10 mg/mL	5 mg to 15 mg by mouth once daily.

a. Name confusion within the Zyrtec product line

Zyrtec Allergy, Children's Zyrtec Allergy, Zyrtec Hives Relief, Children's Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion were identified as being potentially confused with one another. All products in the new Zyrtec contain "Zyrtec", and some have overlapping descriptors (such as "Allergy" and "Hives Relief") in the proprietary name.

The adult Zyrtec and Children's Zyrtec Allergy and Zyrtec-D Allergy & Congestion contain the same active ingredient (cetirizine HCl), and share similar numerical strengths (5 mg vs. 5 mg/120 mg), usual dose (1 tablet), route of administration (oral), and dosage form (tablet). Because the same active ingredient is shared with all products, if they were confused with one another, there would not be a clinically significant outcome because they contain the same active ingredient.

Although Zyrtec-D Allergy & Congestion and Zyrtec Allergy have some overlapping product characteristics, confusion between the two products may be minimized since Zyrtec-D Allergy & Congestion will be located behind the pharmacy counter because it contains pseudoephedrine. Thus, consumers will have to ask for the Zyrtec-D product rather than just pulling it off of the retail shelf. DMETS recommends educating consumers and healthcare providers on the differences between Zyrtec Allergy and Zyrtec-D Allergy & Congestion in order to minimize confusion between the two products.

Overall, we anticipate potential confusion during the initial product launch due to the product line similarities. But this confusion may be minimized by well designed labeling and packaging along with education of consumers and healthcare providers.

b. Existing name confusion with Zyrtec products

As previously mentioned in section IIC, post-marketing surveillance has shown that there have been medication errors with prescription Zyrtec and primarily Zantac and Zyprexa.

1. Zyrtec and Zantac

Thus far, the medication errors between Zyrtec and Zantac have only involved the oral solution dosage form. The errors may be attributed to name similarity: Zyrtec and Zantac begin with the same letter (Z) and have a similar suffix ("tec" vs. "tac"). Additionally, the overlap in prescribing dose (5 mL or 1 tsp), and dosage form (syrup), along with the storage proximity of the products, may have contributed to confusion between these two products.

Once Zyrtec becomes OTC, DMETS anticipates fewer prescriptions over time for Zyrtec as it becomes more widely known that Zyrtec is available OTC. Since Zyrtec/Children's Zyrtec Allergy and Zyrtec/Children's Zyrtec Hives Relief will be stocked on retail shelves rather than on the pharmacy shelf, the opportunity for selection errors between Zyrtec and Zantac (syrup) may decrease. Additionally, when considering the potential for confusion to occur in the OTC setting, DMETS notes that Zyrtec Allergy tablets and Zantac (OTC) tablets are unlikely stored side-by-side because they have different indications (allergy relief vs. antacid). Although the prescription to OTC switch of Zyrtec may decrease the errors between Zyrtec and Zantac, name confusion may still occur between these products due to orthographic or phonetic confusion. Because we cannot predict the outcome of the prescription to OTC switch of Zyrtec, we recommend an educational campaign (e.g., advertisements, "Dear Healthcare Provider" letter, etc.) for healthcare providers and consumers to inform them of the new Zyrtec OTC product line.

2. Zyrtec and Zyprexa

Medication errors between Zyrtec and Zyprexa can be attributed to name similarities: the same prefix "Zy" and overlapping strengths (5 mg and 10 mg), dosage form (tablets), dosing interval (QD), and storage proximity on pharmacy shelves.

Since Zyrtec will be available OTC, this may help to minimize shelf selection errors between the two products because they will no longer be stored in close proximity. Although DMETS anticipates that the number of prescriptions for Zyrtec will decrease once it becomes OTC, prescriptions for Zyrtec may not be completely eliminated. Thus, it is still conceivable that name confusion may still occur between Zyprexa and Zyrtec. Because we cannot predict the outcome of the prescription to OTC switch of Zyrtec, we recommend an educational campaign (e.g., advertisements, "Dear Healthcare Provider" letter, etc.) for healthcare providers and consumers to inform them of the new Zyrtec OTC product line.

c. Misleading nature of Hives Relief

DMETS believes the proprietary name, "Hives Relief" is misleading because it implies the product will relieve hives, however the "Use" section of the label only indicates the product is intended to relieve the **itching** due to hives. Therefore, the name "Hives Relief" is fanciful and misrepresents the intended indication for use of the medication. Although drug products exist which contain the descriptor "Hives Relief", DMETS maintains its objection to the use of this descriptor in the proprietary names Zyrtec Hives Relief and Children's Zyrtec Hives Relief due to their misleading implications.

E. PACKAGING & LABELING

DMETS is concerned that selection errors may occur due to the similar trade dress of the Zyrtec OTC product line. Due to the similarity in appearance of the Zyrtec products, and the likelihood that Zyrtec products will be stored in close proximity on the retail shelves, we anticipate that shelf selection errors will occur. Therefore, in order to minimize potential selection errors, we recommend differentiating the indications (e.g., allergy vs. hives relief), and patient population (e.g., children) on the packaging. Please refer to the labeling recommendations in section III.

III. COMMENTS TO THE SPONSOR

DMETS does not recommend the use of the proprietary name Zyrtec Hives Relief and Children's Zyrtec Hives Relief because it is misleading. DMETS believes the proprietary name, "Hives Relief" is misleading because it implies the product will relieve hives, however the "Use" section of the label only indicates the product is intended to relieve the **itching** due to hives. Therefore, the name "Hives Relief" is fanciful and misrepresents the intended indication for use of the medication. Although drug products exist which contain the descriptor "Hives Relief", DMETS maintains its objection to the use of this descriptor in the proprietary names Zyrtec Hives Relief and Children's Zyrtec Hives Relief due to their misleading implications.

Although DMETS has no objections to Zyrtec Allergy, Children's Zyrtec Allergy, and Zyrtec-D Allergy & Congestion, we recommend an educational campaign prior to product launch and during product launch to inform practitioners and consumers of the switch from prescription to OTC status. DMETS also has concerns with name confusion within the Zyrtec product line, and with existing name confusion with Zyrtec products. Additionally, we are concerned that errors may occur due to the labeling and packaging of the Zyrtec OTC product line.

1. Name confusion within the Zyrtec product line

   Zyrtec Allergy, Children's Zyrtec Allergy, Zyrtec Hives Relief, Children's Zyrtec Hives Relief, and Zyrtec-D Allergy & Congestion were identified as being potentially confused with one another. All products in the new Zyrtec contain "Zyrtec", and some have overlapping descriptors (such as "Allergy" and "Hives Relief") in the proprietary name.

   The adult Zyrtec and Children's Zyrtec Allergy and Zyrtec-D Allergy & Congestion contain the same active ingredient (cetirizine HCl), and share similar numerical strengths (5 mg vs. 5 mg/120 mg), usual dose (1 tablet), route of administration (oral), and dosage form (tablet). Because the same active ingredient is shared with all products, if they were confused with one another, there would not be a clinically significant outcome because they contain the same active ingredient.

   Although Zyrtec-D Allergy & Congestion and Zyrtec Allergy have some overlapping product characteristics, confusion between the two products may be minimized since Zyrtec-D Allergy & Congestion will be located behind the pharmacy counter because it contains pseudoephedrine. Thus, consumers will have to ask for the Zyrtec-D product rather than just pulling it off of the retail shelf. DMETS recommends educating consumers and healthcare providers on the differences between Zyrtec Allergy and Zyrtec-D Allergy & Congestion in order to minimize confusion between the two products.

2. Existing name confusion with Zyrtec products

   Post-marketing surveillance has shown that there have been medication errors with prescription Zyrtec and primarily Zantac and Zyprexa.

   a. Zyrtec and Zantac

      Thus far, the medication errors between Zyrtec and Zantac have only involved the oral solution dosage form. The errors may be attributed to name similarity: Zyrtec and Zantac begin with the same letter (Z) and have a similar suffix ("tec" vs. "tac"). Additionally, the overlap in prescribing dose (5 mL or 1 tsp), and dosage form (syrup), along with the storage proximity of the products, may have contributed to confusion between these two products.

      Once Zyrtec becomes OTC, DMETS anticipates fewer prescriptions over time for Zyrtec as it becomes more widely known that Zyrtec is available OTC. Since Zyrtec/Children's Zyrtec Allergy and Zyrtec/Children's Zyrtec Hives Relief will be stocked on retail shelves rather than on the pharmacy shelf, the opportunity for selection errors between Zyrtec and Zantac (syrup) may decrease. Additionally, when considering the potential for confusion to occur in the OTC setting, DMETS notes that Zyrtec Allergy tablets and Zantac (OTC) tablets are unlikely stored side-by-side because they have different indications (allergy relief vs. antacid). Although the prescription to OTC switch of Zyrtec may decrease the errors between Zyrtec and Zantac, name confusion may still occur between these products due to orthographic or phonetic confusion. Because we cannot predict the outcome of the prescription to OTC switch of Zyrtec, we recommend an educational campaign (e.g., advertisements, "Dear Healthcare Provider" letter, etc.) for healthcare providers and consumers to inform them of the new Zyrtec OTC product line.

b. Zyrtec and Zyprexa

Medication errors between Zyrtec and Zyprexa can be attributed to name similarities: the same prefix "Zy" and overlapping strengths (5 mg and 10 mg), dosage form (tablets), dosing interval (QD), and storage proximity on pharmacy shelves.

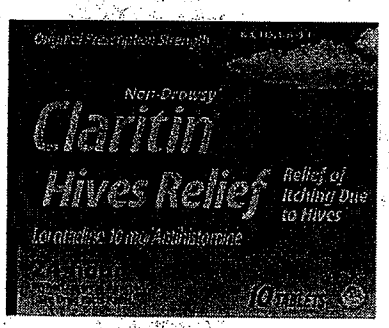
Since Zyrtec will be available OTC, this may help to will minimize shelf selection errors between the two products because they will no longer be stored in close proximity. Although DMETS anticipates that the number of prescriptions for Zyrtec will decrease once it becomes OTC, prescriptions for Zyrtec may not be completely eliminated. Thus, it is still conceivable that name confusion may still occur between Zyprexa and Zyrtec. Because we cannot predict the outcome of the prescription to OTC switch of Zyrtec, we recommend an educational campaign (e.g., advertisements, "Dear Healthcare Provider" letter, etc.) for healthcare providers and consumers to inform them of the new Zyrtec OTC product line.

3. Packaging, Label, and Labeling Comments

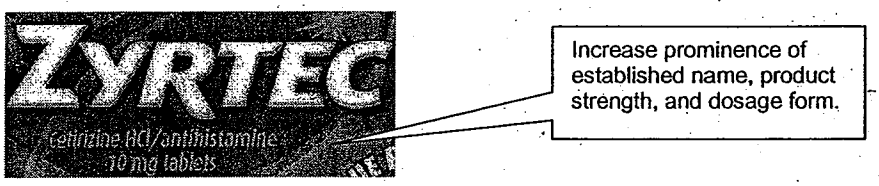
DMETS is concerned that selection errors may occur due to the similar trade dress of the Zyrtec OTC product line. Due to the similarity in appearance of the Zyrtec products, and the likelihood that Zyrtec products will be stored in close proximity on the retail shelves, we anticipate that shelf selection errors will occur. Therefore, in order to minimize potential selection errors, we recommend differentiating the indications (e.g., allergy vs. hives relief), and patient population (e.g., children) on the packaging. Although DMETS objects to the names Zyrtec Hives Relief and Children's Zyrtec Hives Relief, we will include comments on the proposed names in the event that they are approved. Please refer to the labeling recommendations below.

A. GENERAL COMMENTS

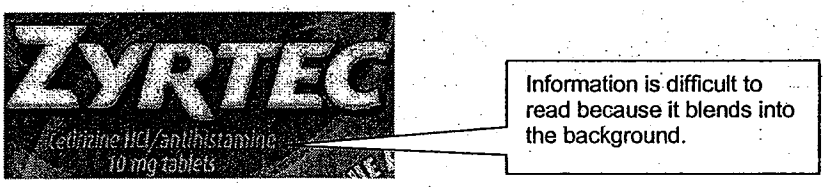
1. DMETS notes that the Sponsor proposes to have different descriptors in conjunction with the proprietary name (e.g., Hives Relief, Allergy, and Allergy & Congestion). Since these descriptors will be part of the proprietary name, the descriptors should appear in closer proximity to or in conjunction with the proprietary name. For example, Claritin Hives Relief is an approved OTC product. The descriptor "Hives Relief" appears in close proximity to "Claritin" which clarifies the proprietary name as "Claritin Hives Relief".



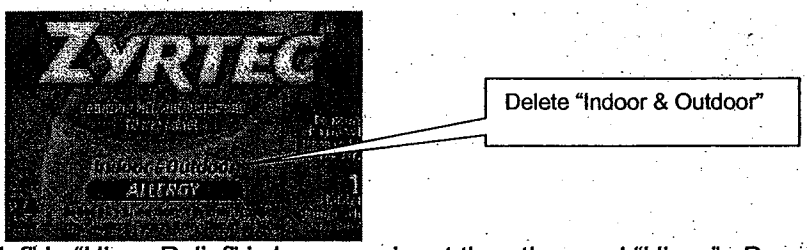
2. Since there are several antihistamine OTC products that contain different active ingredients, we recommend increasing the prominence of the established name (cetirizine HCl and cetirizine HCl/pseudoephedrine HCl), product strength, and dosage form in order to help patients and practitioners differentiate between the different products and active ingredients. DMETS recommends that the established name should be at least ½ the size of the proprietary name in order to improve readability.



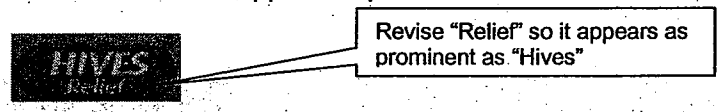
3. The yellow color of the established name and product strength blends into the red/orange background making it difficult to read. Revise the colors in order to improve readability.



4. The terms "Indoor & Outdoor" associated with the descriptors "Allergy" and "Allergy & Congestion" appears on each panel of drug product. "Indoor & Outdoor" is not qualified on the panels, thus consumers may not understand its meaning. Since "Indoor & Outdoor" is qualified on the Drug Facts section on the carton, we recommend deleting "Indoor & Outdoor" from the panels on the carton and from the principle display panel of the container labels.



5. The word "Relief" in "Hives Relief" is less prominent than the word "Hives". By emphasizing the word, "Hives", consumers may overlook "Relief". This can be misleading in that it may lead consumers to believe that the product will treat hives rather than provide hives relief. Therefore, we recommend revising the word "Relief" to appear as prominent as the word "Hives".

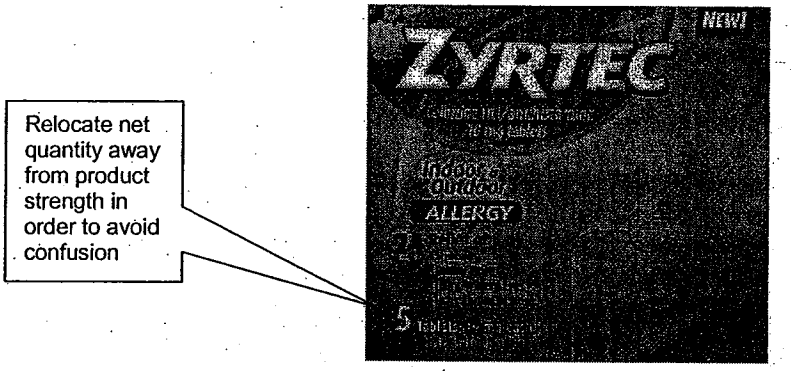


6. We acknowledge that the Sponsor has color coded the word "Children's" with the target age range (2 yrs & older [blue], 6 yrs & older [yellow]). However, it is difficult to read the blue font due to poor contrast with the blue background compared to the yellow font/background (see comparison below). Revise the font and/or the background in order to improve readability. Avoid using a color scheme similar to "6 yrs & older" to provide adequate visual distinction between the two formulations.

7. Increase the prominence of "2 yrs & older" and "6 yrs & older" on the labeling in order to improve visual differentiation between the specific age groups.

8. The term "NEW!" should remain on the carton no longer than 6 months.

9. Decrease the prominence of the net quantity located towards the bottom left side of the labels as it appears more prominent than the product strength. Relocate the net quantity away from the product strength in order to minimize confusion between the net quantity and product strength, particularly since there is an overlap between the net quantity and product strength.

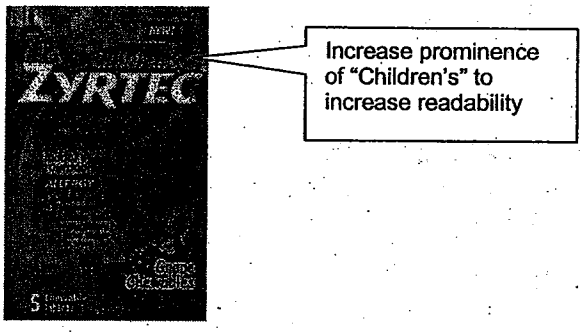


B. CHILDREN'S ZYRTEC ALLERGY and CHILDREN'S ZYRTEC HIVES RELIEF

1. Carton Labeling

a. Oral Solution (15 mL and 118 mL bottles)

i. The word "Children's" may be overlooked as it is not as prominent as "Zyrtec" and it is poorly contrasted with the background. In order to differentiate Children's Zyrtec from the adult Zyrtec product, provide adequate contrast, and increase the prominence of the word "Children's" to the same prominence as "Zyrtec" in order to improve readability.



ii. The 118 mL carton indicates that a dosing cup is included with the drug product. However, the 15 mL carton (professional sample) does not indicate whether or not dosing cups are included in the carton. DMETS is concerned that if dosing cups are not included in the 15 mL carton, caregivers/consumers will not be able to accurately dose the medication. We recommend including a dosing cup for each bottle in the 15 mL sample carton (total of 12 dosing cups).

iii. The statement "2yrs. & older" is difficult to read because the dark blue font has poor contrast with the blue background. Either revise the color of the font or the color of the background so that there is more contrast which should improve readability.

iv. The target age group does not appear on the professional sample of the 15 mL bottle. For consistency purposes, include "2 yrs. & older" on the professional sample carton.

b. Chewable Tablets (5 mg and 10 mg)

i. See General Comments.

ii. See comment B1a(i).

2. Container Labels

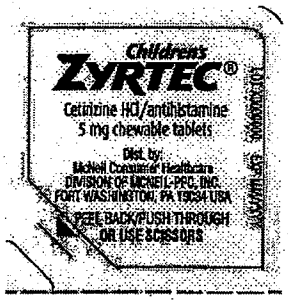
a. Oral Solution (15 mL and 118 mL bottles)

i. See General Comments.

ii. See comments B1a(i) and B1a(iii).

b. Chewable Tablets (5 mg and 10 mg blisters)

i. It is difficult to differentiate the two strengths as they appear identical (same font, size, color). Revise the presentation of product strengths so they are clearly differentiated from one another by using contrasting color, boxing, or by some other means.



ii. Although it is not required, DMETS recommends that the Sponsor consider adding a barcode to the individual blisters in the event that the drug product is used in the hospital setting.

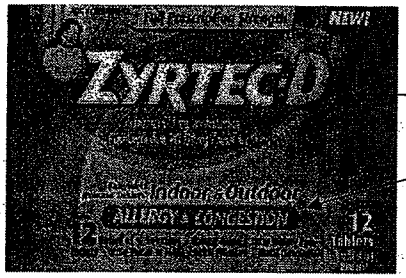
iii. The blisters lack the descriptor in the proprietary name (Allergy or Hives Relief). Include these descriptors as they are part of the proprietary name, and they help to distinguish the products from one another.

C. ZYRTEC-D ALLERGY & CONGESTION

1. Carton Labeling (50 tablet packet dispenser and 12 tablet carton)

a. See General Comments A1, A2, A3, A4, and A8.

b. We acknowledge that the sponsor has highlighted the "-D" of Zyrtec-D in yellow, and the word "Congestion" in Allergy & Congestion in an effort to differentiate Zyrtec-D Allergy & Congestion from Zyrtec Allergy. However, the "-D" may be overlooked because it appears more subdued rather than highlighted. Revise the color of the "-D" so it appears in white; this will help with the continuous flow the name, and may minimize overlooking the "-D". Additionally, revise the word "Congestion" so that it appears in white as well, for continuity purposes.



c. Relocate the dosage form (extended-release tablets) in closer proximity to the established name and product strength in order for consumers to easily identify that this is an extended-release product.

2. Container Labels (professional sample blister and individual retail blister)

a. Professional Sample

i. See General Comments A1 through A4.

ii. See comments C1b and C1c.

b. Individual Retail Blister

The individual blister lacks the descriptor (Allergy & Congestion) in the proprietary name. Include this descriptor as it is part of the proprietary name.

D. ZYRTEC (ALLERGY and HIVES RELIEF)

1. Carton

a. Professional Sample 10 mg (Allergy) 50 count

See General Comments A1, A2, A3, A4, A8, and A9.

b. 5 mg and 10 mg (Hives Relief) 14 count

See General Comments A1, A2, A3, A5, A8, and A9.

2. Clamshell Carton (10 mg- 5 count (Allergy), 5 mg and 10 mg- 14 count (Allergy), 10 mg- 30 count (Allergy), and 10 mg- 75 count (Allergy))

a. DMETS questions which carton the 5 mg and 10 mg 14 count (allergy) tablets will go into. The sponsor did not provide a carton that goes along with this clamshell carton. Please provide clarification.

b. It is difficult to differentiate the 5 mg and 10 mg clamshells because they appear identical. Clearly differentiate the product strength by contrasting color, boxing, or some other means.

c. See General Comments A1, A2, A3, A4, A8, and A9.

3. Container Labeling (Professional Sample Blister, Individual Retail Blister, 30 count bottle)

a. Professional Sample Blister (10 mg- Allergy)

See General Comments A1, A2, A3, A4, and A9.

b. Individual Retail Blister

i. The individual blister lacks the descriptor (Allergy or Hives Relief) in the proprietary name. Include this descriptor as it is part of the proprietary name.

ii. The Sponsor has only submitted one strength for individual retail blister. Since there will be two strengths, ensure that the product strengths (5 mg and 10 mg) are clearly differentiated from one another by using contrasting color, boxing, or by some other means.

c. 30 count bottle

i. See General Comments A1 through A3, and A7.

ii. The blue polka dots on the principle display of the container label are distracting and make the label difficult to read. Delete the polka dots in order to improve readability.

iii. DMETS notes that the value carton indicates there will be a 45 count bottle. However, we did not receive labeling for a 45 count bottle. Please submit this labeling for review and comment.

E. DOSING CUP

1. Dosing Cup

DMETS notes the dosing cup is dosed from 2.5 mL (½ teaspoon) up to 15 mL (3 teaspoons) in increments of 2.5 mL (½ teaspoon). Since the maximum dose for children is 5 mL and for adults is 10 mL, we recommend revising the dosing cup so that it provides three doses: 2.5 mL (½ teaspoon), 5 mL (1 teaspoon), and 10 mL (2 teaspoons). This may help to minimize dosing errors. Delete the 7.5 mL, 12.5 mL, and 15 mL markings and corresponding teaspoon markings, since these doses are inconsistent with the labeling.

F. PATIENT PACKAGE INSERT (Zyrtec Allergy and Zyrtec Hives Relief)

1. See General Comments A1 through A5.

Appendix A

Zyrtec Allergy prescription study results

Written Inpatient	Written Outpatient	Verbal
Zyrtec Allergy	Zyrtec Allergy	Zertec Allergy
Zyrtec Allergy	zyrtec allergy	Zetic Allergy
ZYRTEC ALLERGY	Zyrtec Allergy	Zyrtec
Zyrtec Allergy	Zyrtec Allergy	Zyrtec Allergy
Zyrtec Allergy	Zyrtec allergy	Zyrtec Allergy
Zyrtec allergy	Zyrtec Allergy	Zyrtec Allergy
Zyrtec Allergy	Zyrtec allergy	Zyrtec Allergy
Zyrtec Allergy	Zyrtec allergy	
Zyrtec Allergy	Zyrtec Allergy	
Zyrtec Allergy	Zyrtec Allergy	
Zyrtec Allergy	Zyrtec Allergy	
Zyrtec Allergy	Zyrtec Allergy	
Zyrtec Allergy	Zyrtec Allergy	
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		
Zyrtec Allergy		

Appendix B

Zyrtec Hives Relief prescription study results

Written Inpatient	Written Outpatient	Verbal
Zyrtec Hayfever Relief	Zyrtec Hive Relief	Zurtec hives release
Zyrtec Hive Relief	Zyrtec Hives Relief	Zyrtec Highs Release
Zyrtec hive relief	Zyrtec Hives Relief	Zyrtec Hives Relief
Zyrtec Hive Relief	Zyrtec Hives Relief	Zyrtec Hives Relief
Zyrtec Hive Relief	ZYRTEC HIVES RELIEF	Zyrtec timed release
Zyrtec Hive Relief	Zyrtec Hives Relief	Zyrted Hive Relief
Zyrtec Hive Relief	Zyrtec Hives Relief	
Zyrtec Hive Relief	Zyrtec Hives Relief	
Zyrtec Hive Relief	Zyrtec Hives Relief	
Zyrtec Hive Relief	Zyrtec Hives Relief	
Zyrtec Hives Relief	Zyrtec Hives Relief	
Zyrtec Hives Relief	Zyrtec Hives Relief	
Zyrtec Hives Relief	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	
	Zyrtec Hives Relief	

Appendix C

Zyrtec-D Allergy & Congestion prescription study results

Written Inpatient	Written Outpatient	Verbal
Zyrtec D	Zyrtec D Allergy and Congestion	Zerta D
Zyrtec D	Zyrtec-D	Zertec D Allergy and Congestion
Zyrtec D Allergy & Congestion	Zyrtec-D Allergy & Congestion	Zyrtec Allergy and Congestion
Zyrtec D Allergy & Congestion	Zyrtec-D Allergy & Congestion	Zyrtec D
Zyrtec D Allergy & Congestion	Zyrtec-D Allergy & Congestion	Zyrtec D Allergy and Congestion
Zyrtec D Allergy & Congestion	Zyrtec-D Allergy & Congestion	Zyrtec D Allergy and Congestion
Zyrtec D Allergy & Congestion	Zyrtec-D Allergy & Congestion	Zyrtec-D Allergy and Congestion
Zyrtec D Allergy + Congestion	zyrtec-D allergy and congestion	
Zyrtec D Allergy and Congestion	Zyrtec-D Allergy and Congestion	
Zyrtec D Allergy and Congestion	Zyrtec-D Allergy and Congestion	
Zyrtec D allergy and congestion	Zyrtec-D, allergy and congestion	
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec D Allergy and Congestion		
Zyrtec-D Allergy and Congestion		
ZYRTEC-D ALLERGY AND CONGESTION		

Appears This Way
On Original

Appendix D
Narratives of Zyrtec Medication Errors

Medication errors between Zyrtec and Zyprexa								
Pt #	Source ISR, DeRS, USP #	Date of Event or Report (location)	Age / Sex	Product 1 (Intended)	Product 2 (dispensed)	Cause(s)	Outcome / Description	Narrative
1	ISR 4875027	01/05/2006	20 y.o. Male	Zyrtec	Zyprexa 10 mg	Rx for Zyrtec filled with Zyprexa; similar names	Pt had seizure, fell, went to ER, admitted to ICU	This consumer reports that her 20 year old son has been taking Zyrtec (cetirizine) 10 mg daily with no problems for the last five years for allergy symptoms. On [redacted] the patient received a new refill of Zyrtec 10 mg from a new pharmacy because the patient had moved to a new location. On [redacted] it was noticed that the Zyrtec looked different. The pharmacy was called and the patient's mother was told that they received generic Zyrtec. The patient was given the medication on [redacted] and within one to two hours of taking the first tablet from the new refill, the patient became "dopey" and could not keep his eyes open. On [redacted] as the patient's mother was speaking to the physician, the patient experienced a seizure, falling off his chair and breaking his glasses. The patient was taken to the emergency room where he was stabilized and then admitted to the intensive care unit (ICU) due to these events. While in the emergency room, it was found that a dispensing error had occurred because the tablets inside the pharmacy bottle labeled as Zyrtec, were actually determined to be Zyprexa (olanzapine) 10 mg. So the Zyprexa was stopped after one dose due to these events. While in the ICU, on [redacted] the patient's blood pressure was low, heart beat was erratic, and the patient kept fainting with mild seizures. The patient improved and was discharged on [redacted] but as of 25Nov2005, the patient continues to experience confusion, feeling tired, frequent visits to the bathroom and puffy face. This consumer states that the names of the Zyrtec and Zyprexa are too similar and may be a factor in the dispensing error. Additional concomitant medications include atenolol 25 mg, and Catapres TTS3 (clonidine) patch.
2	ISR 4965886	04/05/2006	45 y.o. Male	Zyprexa	Zyrtec	Rx for Zyrtec filled with Zyprexa	Injested x 22 days: dizziness, somnolence	Discovered medication error. Zyprexa dispensed by pharmacist instead of Zyrtec. Ingested Zyprexa 20 mg tabs BID x 22 days. Have experienced significant side affects including dizziness, somolence, speech dificulties, weight gain, hypercholestremia, dry mouth, restlessness, agitation, insomnia. Currently exhibiting s/s 48 hrs after last dose.
3	ISR 5004663 USP 57755	05/16/2006	n/a	Zyrtec 10 mg	Zyprexa 10 mg	Rx for Zyrtec filled with Zyprexa	Injested 3 doses	A patient received 3 doses of Zyprexa 10 mg instead of Zyrtec 10 mg. The prescription was misfiled at a local pharmacy. Patient received the wrong medication. Similar names of the products.
4	ISR 5119247 USP 58068	10/02/2006	12 y.o Male	Zyrtec	Zyprexa 10 mg	Rx for Zyrtec filled with Zyprexa, Rx looked like Zyprexa	Pt felt faint and weak	MD. wrote for Zyrtec - Rx looked like Zyprexa 10 mg dispensed for Zyprexa 10 mg, once daily Pharmacy open 8am-9pm usually 2 Pharmacists - 3-4 technicians - Pharmacy Volume @5 weekly. patient felt faint and weak.

5	ISR 5153044 USP 58111	11/14/2006	n/a	Zyrtec 10 mg	Zyprexa 10 mg	Bubble pack filled with Zyprexa 10 mg instead of Zyrtec 10 mg:; same strengths	Incorrect medication dispensed to pts 24 times	LTC bubble pack filled incorrectly with Zyprexa 10 mg, order for Zyrtec 1.0 mg. Incorrect medication given 24 times by nursing staff. Unknown, pharmacy and facility are "keeping it quiet." Zyrtec vs. Zyprexa 10 mg. Both are the same strength, the nurses must have looked at the first couple of letters and punched the medication out. There is quite a difference in tab size and shape between the two medications, and care should be taken to make sure the proper medication is being dispensed to the patient.
6	ISR 5175427 USP 58186	12/12/2006	n/a	Zyrtec 10 mg	Zyprexa 10 mg	Zyprexa filled for Zyrtec blister card; same strengths	Incorrect medication filled in blister	Monthly cycle fill at a skilled nursing facility the pharmacy I work for services. This is the second month in a row that Zyprexa 10 mg has ended up being filled in a blister card that was supposed to have Zyrtec 10 mg. My coworker found the medication error before swapping the new card for the old one. The card was returned to the pharmacy and the correct medication was sent out later that day. Strength was the same, and the "ZY" was all the technician was looking at before filling the card.
7	ISR 5196811 USP 58341	12/29/2006	37 y.o. Male	Zyrtec 10 mg	Zyprexa 10 mg	Rx for Zyrtec filled with Zyprexa	Pt took 4 doses, experienced side effects	Prescription written and processed for Zyrtec 10 mg was filled with Zyprexa 10mg. Pt took 4 doses , then visited MD, who I'D'd tablets as Zyprexa (vial labeled Zyrtec) Pt suffered side effects from Zyprexa and Incident occurred change shift
8	ISR 5212822 USP 58397	01/18/2007	24 y.o. Femal e	Zyrtec 10 mg	Zyprexa 10 mg	Label correct, medication was filled incorrectly	Pt received 2 doses	Zyprexa was dispensed instead of Zyrtec 10 mg tab. Label tab was correct; fill error. Pt received 2 doses. We have moved the Zyrtec to a different location on the pharmacy shelf. Fill techs were counseled on triple checking bottle when filling. Zyrtec Nomenclature is changed in label computer to alert staff.

9	ISR 5218964 USP 57939	01/23/2007	21 y.o. Male	Zyrtec 10 mg	Zyprexa	Rx for Zyrtec filled with Zyprexa	Pt had a seizure, admitted to ICU	Follow-up (14Aug2006): Last November, a mother of a 21 year-old mentally disabled patient went to have his prescriptions refilled at a pharmacy. The family was new to the area, and was transferring in prescriptions from their old, independent pharmacy that they had previously used for 19 years without incident. She needed to get three prescriptions for her son: atenolol, Catapress (clonidine) TTS 3 and Zyrtec (cetirizine) 10mg. Her son had been taking the combination for five plus years and using the atenolol/Catapress combo to control blood pressure and his hyperactivity, Zyrtec for allergies. The pharmacy transferred the prescriptions in and dispensed them to the patient's mother. She had some remaining quantities at home, so about a week passed before she went to use the new pharmacy prescriptions. When she went to lay out her son's medications in the morning with his breakfast she noticed that the Zyrtec tablet looked was small & round- different than the oblong white tablet she was accustomed to administering to her son. She checked the label on the bottle, and it had the correct name, strength, route, frequency etc. all the same as what appeared on the old label. Thinking that the change was strange, the mother called the pharmacy to see why it looked different. A technician answered the phone, looked up her son's profile on the computer, and explained to her that the medication they gave her was a generic and that's why it looked different. The mother said that the girl never asked her anything about how the medicine looked- just told me "it's generic and that's why it's different". The mother gave the medicine to her son. A short time later she noted that her son's behavior began to change, and he began to act sleepy. She called the pharmacy again and asked to speak to the pharmacist this time. The pharmacist told her that it was generic for Zyrtec and that if she was unhappy with the generic, she could return to the pharmacy and they would replace it with the brand. The mother got off the phone with the pharmacy. Her son continued to get sleepier and so she decided to call his doctor. While explaining the issue and her son's symptoms to the doctor, her son fell out of the kitchen chair and began to have a seizure. The doctor instructed the mother that he would phone an ambulance and to bring the bottle of Zyrtec from pharmacy with him to hospital. She brought the Zyrtec to the emergency department and the doctor took one look at the medication and told the mother that it was not Zyrtec. The mother said that the pharmacy told her that it was the generic for Zyrtec where upon the doctor told her that there is not a generic for Zyrtec. The doctor looked it up on the computer and discovered that it was the highest strength of Zyprexa (olanzapine). Her son was admitted to the Intensive Care Unite (ICU) as they were having a hard time stabilizing his blood pressure (according to mother "low"), heart rate (mom says "irregular"), and seizures. Her son stayed in hospital a couple of days and then was discharged home. No prior history or family history of seizure disorders, has not had seizures since. Since this incident, the mother says that her son's toileting habits have regressed with frequent bouts of bowel/urinary incontinence, which he previously did not experience. This case is considered medically confirmed.

10	ISR 5218963 USP 57945	01/23/2007	6 y.o Femal e	Zyrtec 10 mg	Zyprexa 15 mg	Rx for Zyrtec filled with Zyprexa	Addiction, paranoia, hallucination s, referred to neurologist	This is a regulatory authority registry report from the United States Pharmacopeia (USP) (Reference # 57945). This consumer reports that her 6 year old sister was prescribed Zyrtec (cetirizine), 10 mg tablets daily on an unknown date for an unknown indication. Reportedly, a pharmacy dispensed a prescription containing Zyprexa (olanzapine) instead of Zyrtec (cetirizine) in a Zyrtec box, complete with Zyrtec instruction/booklet. Zyprexa was administered for 29 days, and within that month, the child "went from 50 lbs to 65 lbs, had "a severe chance in addiction, paranoia, hallucinations, and craved this medication." She refused to go to school because "something bad was going to happen to my mommy," and screamed that she saw her grandmother as "a skeleton with no eyes." The child was referred to a neurologist. At the time of the report, the child was being treated as an "addict and in at home on a type of detox patient." She was started on Ativan (Lorazepam) and another medication, and was still having "on and off" episodes of hallucinations and paranoia.
11	ISR 5313693 USP 58807	04/30/2007	8 y.o. Femal e	Zyrtec	Zyprexa	Zyprexa entered instead of Zyrtec; similar names-selected wrong product	Error was not caught when checking rx, no harm	Zyprexa was entered instead of Zyrtec. This error was not caught by pharmacist when checking the prescription. Root cause analysis: - Technician at drop off made the wrong product selection at input. - Pharmacist at final verification failed to detect the drug that had been entered into the computer incorrectly. No harm done Similar names; technician select the wrong product at input.

Medication errors between Zyrtec and Zantac

Pt #	Source/ ISR/ DAERS/ USP #	Date of Event/ Report/ Reaction	Age/ Sex	Product 1 (intended)	Product 2 (dispensed)	Cause(s)	Concomit/ Prescription	Narrative
1	ISR 4728434	07/29/2005	9 y.o. Male	Zyrtec	Zantac	Unknown dispensing error	Lack of effect	This case was reported by a regulatory authority and described the occurrence of dispensing error in a 9-year-old male patient who received Ranitidine hydrochloride (Zantac) syrup over a period of Unknown for allergies. Co-suspect medication included Zyrtec. On an unknown date, the patient started Ranitidine hydrochloride (oral) at 15 mg, unknown dosing. At an unknown time after starting Ranitidine hydrochloride, the patient experienced dispensing error and lack of effect, in which his allergies continued. The outcome of the events is unknown.
2	ISR 4943971	03/13/2006	4 y.o. Male	Zyrtec	Zantac	Rx for Zyrtec filled with Zantac	Received incorrect med for 7 days. Diarrhea, vomiting, hallucinations	Syrup form Zyrtec was prescribed for allergies to 4 year old child. The pharmacy filled the prescription with syrup form Zantac in error. Patient was unaware of error up. Had given usual dose of one teaspoon once a day to the child for aprox. 7 days. The child was complaining of upset stomach, diarrhea, vomiting, and hallucinations, a rare side affect of Zantac. Parent inquired about the medicine to the pharmacy and verified the error. Pediatrician was notified and verified the possible side affects.

3	ISR 5007773	05/22/2006	2 week old Femal/ e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Involuntary movements, seen by neurologist. Possible permanent neurological damages	This case was reported by a lawyer and described the occurrence of dispensing error in a 7 week old female patient who received Ranitidine hydrochloride (Zantac) for gastroesophageal reflux. A physician or other health care professional has not verified this report. Concurrent medical conditions included gastroesophageal reflux. Co-suspect medication included Zyrtec, Reglan and Maalox. Several weeks post-partum, the patient experienced small episodes of vomiting and hiccups. She was diagnosed with gastroesophageal reflux by a pediatrician and was prescribed ranitidine (Zantac), metoclopramide (Reglan) and aluminum hydroxide+magnesium hydroxide (Maalox). On 02 February 2004, the medications were dispensed. After using the medications, the patient began to experience involuntary movements (initially reported by the attorney as seizures). Pursuant to physician orders, metoclopramide was suspended, however the involuntary movements continued. Prior to these events, the patient's parents visited a pediatric gastroenterologist and he confirmed the reflux diagnosis and maintained her on Zantac. He determined that the movements were not related to the reflux condition. The pediatrician recommended a consult with a pediatric neurologist. Upon evaluation in May 2004, the pediatric neurologist diagnosed the events as a result of "profound sleep stage". In September, during a follow-up visit, the gastroenterologist prescribed Zantac again and it was dispensed. The patient began showing difficulty in taking the Zantac recently dispensed, which had not occurred previously. On 20 November 2004, when the parents went to the pharmacy to purchase another medication for the patient, they showed the pharmacist the Zantac bottle dispatched in February and the one dispatched in September. They explained to the pharmacist that the patient did not want to take the new medication. At that moment, the pharmacist on duty informed the parents that the medication dispatched in February was cetirizine (Zyrtec) rather than ranitidine (Zantac). Upon this new information, the parents once again visited the pediatric neurologist who confirmed that the involuntary movements that the patient experienced could be related to the side effects of Zyrtec and he gave them a referral to submit the patient to electroencephalogram (EEG) testing. Diagnostic testing included EEG, computed tomography (CT) scan and blood tests (results were not provided). It was reported that Zyrtec, which aggravated the reflux condition, was discontinued. The neurologist's preliminary report indicated that the patient could possibly have some permanent neurological damages. This case was assessed as medically serious by GSK.
4	ISR 5013523 USP 57818	05/25/2006	3 y.o. Femal e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec; look-alike and sound-alike names	Error caught prior to administration	A prescription was presented for Zantac Liquid. The technician removed Zyrtec Syrup from shelf and entered in the pharmacy computer system. The same technician filled the prescription with Zyrtec Syrup. Prescription and bottle of medication was reviewed and verified by the pharmacist. The prescription was picked up by patient's family, who returned within 30 minutes, having identified the dispensing error. The prescription was corrected and re-dispensed. Misinterpretation of medication due to look alike/sound alike name.

5	ISR 506418	07/28/2006	10 y.o. Femal e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Pt experienced headaches, reflux, urination	This case was reported by a consumer and described the occurrence of bronchitis in a 10-year-old female patient who received Ranitidine hydrochloride (Zantac) syrup over a period of 9 years for gastroesophageal reflux disease. A physician or other health care professional has not verified this report. The reporter is the patient's mother. The patient's past medical history included acid reflux, cataract and congenital heart defect. Concurrent medical conditions included down's syndrome and hearing loss. Co-suspect medication included Zyrtec. Concurrent medications included lansoprazole (Prevacid) and Antibiotics. On an unknown date, the patient started Ranitidine hydrochloride (oral) at 4 cc twice per day. On 3 January 2006, the patient experienced bronchitis, reflux (nos), increased urination, headache, dispensing error, aspiration and product complaint. Treatment with Ranitidine hydrochloride was continued. At the time of reporting, the events were resolved. The patient was given Zyrtec instead of Zantac syrup and experienced daily headaches, increase urination and severe reflux which caused her to aspirate and develop bronchitis. That events resolved. The product was returned to the pharmacy and after a "sniff test" the pharmacist exchanged the medication for the correct medication. On 03 January 2006, the mother reported the same incident almost happend again. Mother reports that fortunately this time she smelt the medication.
6	ISR 5064176	07/28/2006	10 month old Male	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Pt given 1 dose, experienced vomiting	This case was reported by a consumer and described the occurrence of medication error in a 10-month-old male patient who received Ranitidine hydrochloride (Zantac) syrup over a period of 7 months for gastroesophageal reflux disease. A physician or other health care professional has not verified this report. Concurrent medications included No concurrent medication. On August 2005 the patient started Ranitidine hydrochloride (oral) at 15 ml twice per day. On 22 March 2006, the patient experienced medication error and spitting up. Treatment with Ranitidine hydrochloride was continued. At the time of reporting, the events were resolved. Patient's reports that she was given a prescription of her son's Zantac Syrup and it smelled fruity instead of minty. She only gave her son half a dose, and took the syrup back to the pharmacy for replacement. She received another prescription that smelled minty. Her son had no apparent reaction to the fruity syrup yesterday, but did seem to spit up a little more than usual today. Follow-up information was received on 24 March 2006 via the consumer, who reported that the pharmacy mistakenly dispensed Zyrtec syrup, rather than Zantac syrup as prescribed. The patient received one dose of Zyrtec syrup.
7	ISR 5119231 USP 58140	10/02/2006	n/a	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	unknown	Pharmacy dispensed Zyrtec liquid on a prescription written for Zantac liquid.

8	ISR 5142126 USP 58074	10/30/2006	n/a	Zyrtec	Zantac	Rx for Zyrtec filled with Zantac	Stomach pain, rash	A mother refilled her child's prescription for Zyrtec syrup on February XX, 2006, and began administering the medication on MarhXX, 2005. When she gave the child the medicine, the child refused to take the medication (spit out the dose), saying that it didn't taste or smell like her regular medicine. The mother tasted the medication, and noted that it did taste and smell different to Zyrtec (note: Zantac is minty, Zyrtec is fruity). The mother brought the bottle of medication back to the dispensing pharmacy (Retail Pharmacy), and told the pharmacist about the child's complaints. The pharmacist took the bottle and smelled it. Upon smelling the liquid medication, the pharmacist identified the liquid as Zantac not Zyrtec. While taking the Zantac, the child developed stomach pains and a rash which resolved after discontinuing the Zantac. The mother reported that this pharmacy had made dispensing errors in the past; that included wrong pill counts and dispensing of expired medications. While taking the Zantac, instead of Zyrtec, the child developed stomach pains and a rash which resolved after discontinuing the Zantac.
9	ISR 5151094	11/14/2006	3 month old Male	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Worsening GERD sxs	My son was prescribed Zantac by Dr. [redacted]. The [redacted] filled this prescription with Zyrtec instead. My son had been hospitalized at two weeks of age due to complications with GERD and has been treated with Zantac since that time. His symptoms worsened after three days on Zyrtec, I looked closer at the prescription and realized that it was not the correct medication for my son...I looked on the internet and not only did it say that infants under six months of age are not supposed to be prescribed Zyrtec, but the dose given to my son was high. Not only was he not getting the prescription he needed for his medical condition, but he was also getting an incorrect drug. I then found out that this very same pharmacy recently made this mistake with another infant with a mix up of the same two drugs. I was told by [redacted] that they would file an internal complaint, but they never contacted me. I would like to make certain that this never happens again.
10	ISR 5210829	01/17/2007	5 month old Male	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Difficulty sleeping	This pharmacist reports that a currently 5 month old male consumer began on Zyrtec (cetirizine) 0.5ml thrice a day for gastroesophageal reflux on 11Aug2006. He was supposed to take Zantac but was given Zyrtec by error. He had trouble sleeping on 11Aug2006. On 25Aug2006 mother observed that drug was not working, assuming the drug to be Zantac. The clincal outcome of the event is unknown at the time of the report. He stopped Zyrtec on 25Aug2006. Zyrtec was purchased in the US. Follow-up (05Jan2007): This physician reports that a "5 month old" male patient was given Zyrtec (cetirizine) 0.5ml orally three times a day for gastroesophageal reflux on 11Aug2006. When the patient was given Zyrtec instead of prescribed Zantac for reflux, sleep difficulties ensued. The patient had sleeplessness. The Zyrtec was stopped on 26Aug2006 and the event abated after Zyrtec was stopped. Follow-up Status: Case Closed(11Jan2007) Company Clinical Evaluation: Based on the information provided in the case, this report would not seem to modify the risk-benefit profile of the suspect drug: Zyrtec.

11	ISR 5263657 USP 58522	03/12/2007	n/a	Zantac	Zyrtec	Refill for Zantac filled with Zyrtec	Error caught prior to administration	Medicare is kicking into high gear. People are enrolled into plans but don't have the information. CMS does not have everyone in the system yet. The New auto-enroll program is not working as promised. I am on the phone for 20 minutes (so far) trying to get a customer set up with their new Medicare plan. It is about 1 pm and my full time tech is at lunch. The doctor's offices are coming back from lunch, and are calling in new prescriptions. I am fielding new prescriptions over the phone while still on hold with Medicare. In order to do that, I am not at my normal work station. I am at the far end of the counter on the phone. In order for our techs to have a set schedule day off Wednesdays and Thursdays are 8 hour days for the part time techs. On Mon Tues and Fridays (our busiest days) we have a tech that comes in at 12:30PM. This allows for an unabridged flow of work. The date of the incident is a Wednesday. The flow is interrupted for Lunch breaks. We are on a pace that will take us over — prescriptions for the day. Anything over — prescriptions is a very busy day. I help out in many others locations. I can say with confidence, our location has one of finest and most competent Pharmacy crews. We rarely have wait times exceeding 20 minutes. We always have time to answer questions with our customers, carry on conversations without them every thinking they are bothering us. My crew keeps the flow moving. Only on very rare occasion do I ever catch an error one of my tech make. We fill over —— prescriptions a year and you think about how many things can be wrong with a prescription to make it an error or drug interaction. There is not a day that goes by where we are not catching an error of a prescribing practitioner. On January 2006, a rare instance happened....An Error occurred. I was on the phone away from my normal work flow. My tech was receiving strong pressure from one of our customers about getting his prescription for his child. My tech grabbed a zyrtec bottle instead of the zantac bottle. It was for 4 oz. so she put the label right on the bottle. She threw away the box that had the scan label on it. The bottle does not have the scan bar on it. She then brought it to me in the basket. Since it was a refill, I quickly approved it since I was on the phone. I did not give this particular prescription the full attention it required. Very shortly after the prescription left the store the father discovered the error and called. I verified there was an error, apologized and asked him to return to the store. He immediately came back to the Pharmacy with the original fill bottle and the erroneous prescription that was filled. I had the corrected prescription refilled along with a full refund waiting for him. I sincerely apologized again. The look he gave me was sheer disappointment. It was crushing. How do you tell someone they probably have a better chance winning the lottery than having an error with their prescription in our store? But with the increased pressures we place on the total system, we will see many more. The dad had left the original prescription bottle with us when he left the store. I quickly ran it out to the parking lot to catch him. There were still many doses left in the original fill prescription. Given the time frame of the time of his possession, the amount of doses left in the other bottle, and the discussion with the dad, it was determined that no doses were given. Being shaken up by the event, I quickly filled out the report and put the bottle in the filing cabinet drawer so that it would not be used. I also wanted to reflect on this incident and examine all the factors that could have changed this outcome. Some of these are pretty obvious, while others may not be so subtle.

12	ISR 5273708	03/21/2007	1 month old Femal e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec; Bottles side by side on the shelf	Wrong medication given x 1month	On Jan. 22, 2007 filled a prescription for Zantac 15 MG at the Prescription was written by my child's pediatrician. The child's symptoms were irritability, painful crying. Diagnosis was colic, possible acid reflux. Medication was prescribed to help with acid reflux. On the prescription I put child's date of birth and our phone number. I filled the prescription and began administering 1 ML twice a day -from the directions on the RX label-. One month later on 02/20/2007 I returned for a refill -after Dr.called one in-. Upon returning home I noticed the new medicine smelled very different from the old bottle. After tasting it myself, I concluded it was not the same medication. I returned to the pharmacy on 02/24/2007 or 02/25/2007 and showed the bottles to the pharmacist on duty. He concluded that they were in fact two different medications. He believed that the first bottle filled on 01/22/2007 was Zyrtec not Zantac. Simply because the bottle of Zyrtec is next to the bottle of Zantac on the pharmacy shelf. He said a pharmacist would contact my pediatricians office on Monday 02/26/2007 and let them know of the mix up. No contact was ever made. No known testing has been done on children this young with Zyrtec. Patient appears healthy as of this report, however we have not run any diagnostic testing on patient. Questionable medication bottle remains in my possesion as of this report.
13	ISR 5297490 USP 58721	04/10/2007	8 y.o. Femal e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec; side by side on the shelf	Vomiting	Zantac was prescribed and Zyrtec was dispensed. Technician filled Rx liquid sent to R.Ph for verification. Rx was dispensed, taken by patient, and thought by mother tongue smelled differently than the first filling. We have since then separated stock on shelves and put red plastic markers on them. Also bottle is passed to RPh and bar-coding is used. Patient had some vomiting and lost one month of proper therapy
14	ISR 5297394 USP 58637	04/10/2007	2 month old Femal e	Zantac	Zyrtec	Rx for Zantac filled with Zyrtec	Vomiting, irritable	My 2 month old daughter was prescribed Zantac Syrup 15 mg/mL for reflux. I was given Zyrtec Syrup 1 mg/mL by mistake. I have a Zyrtec bottle with a Zantac pharmacy label on it. Her symptoms were what I would describe as colic. She Spit up out the nose and mouth, stomach pains, she was VERY fussy, inconsolable crying, loss of accommodation - pupil dilation, dry mouth.

Medication errors between Zyrtec and Miscellaneous drugs

PT	Sponsor ISR / OMPS USP #	Date of Event or Report (location)	Age / Sex	Product 1 (intended)	Product 2 (dispensed)	Cause(s)	Outcome / Description	Narrative
1	ISR 4910661	02/10/2006	Femal e	Zyrtec 10 mg	Norvasc 10 mg	Same size and shape bottles. Bottles same blue color	Administered for a few days, No harm	The wrong medication was filled and given to a patient who took some of the medication for a few days and noticed it looked different than usual and called the pharmacy. The prescription was filled on a busy weekday. The patient had no adverse effects that we are aware of, but was quite upset. The bottles of the medication dispensed and the medication that was supposed to be dispensed looked the same except for the drug name. Both were blue marked bottles the same size and shaped and the medications both contained 10 mg tablets of the drugs.

2	ISR 5119314 USP 58069	10/02/2006	21 y.o. Femal e	Zyrtec	Zyrtec-D	Rx for Zyrtec filled with Zyrtec-D, different tablet size	Error occurred, medication not administered	Patient recognized tablet as different and returned to pharmacy - none ingested
3	ISR 5122946	10/05/2006	39 y.o Femal e	Zyrtec 10 mg	Zetia 10 mg	Same color bottles, side by side on shelf	Error occurred, medication not administered	This error occurred due to look-alike/sound-alike medications. The pharmacy filled a prescription for Zyrtec 10 mg with Zetia 10 mg. The pharmacist stated that the bottles of the 2 medications were the same color and situated on the same shelf next to one another. The patient did not take any of the Zetia. The patient discovered the error when consolidating the new Zyrtec tablets with the remaining Zyrtec from a previous prescription. Both tablets are oblong and white in color. The error was caught and corrected but this type of error can occur to others in the future.

4	ISR 5313735	04/30/2007	n/a	Zyrtec 10 mg	Zetia 10 mg	Poor handwriting, misspelled drug name, overlapping doses	Error caught prior to administration	I am an adjunct clinical nursing instructor for junior and senior baccalaurate students. About one month ago a near miss occurred. My student was at the bedside and was identifying each drug to the patient before administration as is my practice. When he identified Zetia, the patient stated that she did not take that medication. The student rechecked the drug as part of the siemens medication administration system. It met all the criteria. The patient was asked to state all of the medications she usually takes on a regular basis. The patient stated she took Zyrtec. Because of the patient's statement we proceeded to check the chart for the actual order of the medication. When I located the original hand written order it was obvious how the name of the medication was misread. I called the pharmacist and reviewed the near miss incident. She and I concurrently reviewed the original order (she had the faxed copy sent to the pharmacy when the order was initially processed). The pharmacist's only question was who would report this incident. I used the online incident tool used at the location as another teaching experience for the student. He observed me completing the numerous screens as part of the reporting process. He counted at least 12 screens that had to be completed for incident reporting. The length of the report tool and the time to complete it are significant obstacles in reporting errors and near misses. The nurses (the unit nurse manager, charge nurse and clinical specialist) did not receive any feedback on this incident report. The nurse manager received limited information in an indirect, casual manner. The root cause was determined to be the physician's poor penmanship and misspelling as primary factors. An additional factor was improper use of a preprinted order set. At the bottom of the preprinted order set, there is space for 1 or 2 additional drugs to be written, the offending physician had squeezed nine medications, dosages, timing in that space. I also want to add that none of the staff nurses were willing to make that report because of personality/behavioral issues with that physician. I was able to report the error because I do not have a continuous relationship with the physician. In fact I demonstrated my willingness to stand up and advocate for the staff nurses who would have suffered negative consequences if they had submitted the incident report. Also, the usual dosages of Zetia and Zyrtec are both 10 mgs so that added to the mistake entered by the pharmacy. As usual, the nurse at the bedside SAVED THE DAY! I have a colleague who was part of a transitional team that implemented MAK at another location. She said that the pharmacists/pharmacy department had no idea how often the bedside nurse intervenes to prevent medication errors from occurring. The usual dosages of Zetia and Zyrtec are both 10 mgs so that added to the mistake entered by the pharmacy. The root cause was determined to be the physician's poor penmanship and misspelling as primary factors. An additional factor was improper use of a preprinted order set.

5	ISR 5355646 USP 58850	06/12/2007	22 y.o. Femal e	Zyrtec 10 mg	Zetia 10 mg	Failure to follow re-stocking procedures, same size shape, and color, bottles	Headaches, difficulty breathing	Zetia 10 mg was dispensed instead of Zyrtec 10 mg on SeptemberXX, 2006. Both pharmacist and technician are involved in this case. The filling technician failed to follow the procedure for handling returned to stock (RTS) products when dispensing from RTS bottle by not comparing the 2 products visually and by scanning the bar codes of the RTS bottle vs. the stock bottle. She threw the RTS bottle away and left the stock bottle of Zyrtec for the verifying. The pharmacist, myself, quickly looked over the pills in the bottle. They were the same general size, shape and color. I checked the drug name, strength and NDC number of the stock bottle. No harm to patient, but the patient complained of having headaches, difficult breathing and not feeling right. Look-alike product.

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

/s/

Kellie Taylor
11/6/2007 05:17:42 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
11/7/2007 02:59:48 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/7/2007 03:00:24 PM
DRUG SAFETY OFFICE REVIEWER

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*: Division of Medication Errors and Technical Support (DMETS)

FROM: Elaine Abraham, RPM
Div. of Nonprescription Clinical Evaluation, WO22, Rm. 5410

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
February 15, 2007		19-835 SE6-022		January 15, 2007

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Zyrtec Allergy (cetirizine HCl tablets)	Med	Antihistamine	August 15, 2007

NAME OF FIRM: Pfizer

REASON FOR REQUEST

I. GENERAL

☐ NEW PROTOCOL
☐ PROGRESS REPORT
☐ NEW CORRESPONDENCE
☐ DRUG ADVERTISING
☐ ADVERSE REACTION REPORT
☐ MANUFACTURING CHANGE/ADDITION
☐ MEETING PLANNED BY
☐ PRE--NDA MEETING
☐ END OF PHASE II MEETING
☐ RESUBMISSION
☐ SAFETY/EFFICACY
☐ PAPER NDA
☐ CONTROL SUPPLEMENT
☐ RESPONSE TO DEFICIENCY LETTER
☐ FINAL PRINTED LABELING
☐ LABELING REVISION
☐ ORIGINAL NEW CORRESPONDENCE
☐ FORMULATIVE REVIEW
X OTHER *(SPECIFY BELOW)*: Trade name review only

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

☐ DISSOLUTION
☐ BIOAVAILABILTY STUDIES
☐ PHASE IV STUDIES
☐ DEFICIENCY LETTER RESPONSE
☐ PROTOCOL-BIOPHARMACEUTICS
☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
☐ SUMMARY OF ADVERSE EXPERIENCE
☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL	☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:
We are requesting a trade name review of the name "**Zyrtec Allergy**". The labeling can be found in the electronic document room (EDR). Please limit your review to consideration of the trade name only. ONP is reviewing all other aspects of the label (principal display panel, Drug Facts content and format etc.). The PDUFA date for this NDA is November 16, 2007. Please contact me at 796-0843 if you have any questions.

SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one)
{See appended electronic signature page}	☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

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

/s/

Elaine Abraham
2/16/2007 12:54:55 PM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*: Division of Medication Errors and Technical Support (DMETS)

FROM: Elaine Abraham, RPM
Div. of Nonprescription Clinical Evaluation, WO22, Rm. 5410

DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
February 15, 2007		19-835 SE6-022		January 15, 2007

NAME OF DRUG	PRIORITY CONSIDERATION	CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
Zyrtec Hives Relief (cetirizine HCl tablets)	Med	Antihistamine	August 15, 2007

NAME OF FIRM: Pfizer

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE--NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- X OTHER *(SPECIFY BELOW)*: Trade name review only

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

- ☐ CLINICAL
- ☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:

We are requesting a trade name review of the name "**Zyrtec Hives Relief**". The labeling can be found in the electronic document room (EDR). Please limit your review to consideration of the trade name only. ONP is reviewing all other aspects of the label (principal display panel, Drug Facts content and format etc.). The PDUFA date for this NDA is November 16, 2007. Please contact me at 796-0843 if you have any questions.

SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one)
{See appended electronic signature page}	☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER

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

/s/

Elaine Abraham
2/16/2007 12:50:35 PM