CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

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Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	December 8, 2010
From:	Yelena Maslov, Pharm.D., Safety Evaluator Division of Medication Error Prevention and Analysis
Through:	Zachary Oleszczuk, Pharm.D., Team Leader Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis
Subject:	Proprietary Name Review
Drug Name(s) and Application Type/Number:	**Allegra Allergy** (Fexofenadine HCl) Tablets 60 mg, 180 mg **Children's Allegra Allergy** (Fexofenadine HCl) Tablets 30 mg **Allegra Hives** (Fexofenadine HCl) Tablets)60 mg, 180 mg **Children's Allegra Hives** (Fexofenadine HCl) Tablets 30 mg NDA 201613 **Children's Allegra Allergy** (Fexofenadine HCl) Orally Disintegrating Tablets 30 mg **Children's Allegra Hives** (Fexofenadine HCl) Tablets Orally Disintegrating Tablets 30 mg NDA 021909/S-003 **Children's Allegra Allergy** (Fexofenadine HCl) Suspension 30 mg/5 mL **Children's Allegra Hives** (Fexofenadine HCl) Suspension 30 mg/5 mL NDA 201373
Applicant:	Sanofi-Aventis US, Inc
OSE RCM #:	2010-1058, 2010-1059, 2010-1060, and 2010-1061

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

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EXECUTIVE SUMMARY

This review summarizes the proprietary name evaluation for four proprietary names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives in the Allegra over-the-counter product line for the switch from prescription to over-the counter status. These products are the single active ingredient fexofenadine HCl. Allegra Allergy and Allegra Hives products are available as tablets. The Children's products are available as tablets, orally disintegrating tablets, and oral solution.

Our proprietary name risk assessment did not identify concerns that would render these four names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives and Children's Allegra Hives, unacceptable based on the product characteristics and safety profile known at the time of this review. Thus, the Division of Medication Error Prevention and Analysis (DMEPA) finds these proprietary names acceptable (See Section 4 for Discussion).

DMEPA considers this a final review; however, if approvals of the NDAs are delayed beyond 90 days from the date of this review, the Division of Non-Prescription Clinical Evaluation should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date. Additionally, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

1 BACKGROUND

1.1 INTRODUCTION

Sanofi-Aventis submitted a request on May 14, 2010, for DMEPA to evaluate the proposed proprietary names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives, regarding potential name confusion with other proprietary or established drug names in the usual practice setting. Additionally, DMEPA considers the Division of Drug Marketing Advertising and Communications (DDMAC) promotional assessment of the name. The applicant also submitted labels and labeling for the product lined as a part of the original NDA applications, which are being reviewed separately under a separate cover (OSE-RCM #2010-1112, 2010-1115, 2010-1116, 2010-1117, 2010-1120, and 2010-1121.)

1.2 REGULATORY HISTORY

The Applicant proposes to switch the Allegra product line from prescription status to non-prescription status. Currently, the Allegra product line contains six approved NDA applications for the following products:

Table 1: Allegra Product line Regulatory History

Proprietary name of Allegra family product	Established Name and Dosage Form	NDA #	Approval Date
Allegra	(Fexofenadine HCl) capsules	NDA 020625	07/25/1996
Allegra-D	(Fexofenadine HCl and Pseudoephedrine HCl) tablets	NDA 020786	12/24/1997
Allegra	(Fexofenadine HCl) tablets	NDA 020872	02/25/2000
Allegra-D 24 Hour	(Fexofenadine HCl and Pseudoephedrine HCl) tablets	NDA 021704	10/19/2004
Allegra	(Fexofenadine HCl) Suspension 6 mg/mL	NDA 021963	10/16/2006
Allegra	(Fexofenadine HCl) Orally Disintegrating Tablets	NDA 021909	07/26/2007

DMEPA found the proprietary names Allegra-D 12 Hour Allergy and Congestion and Allegra-D 24 Hour Allergy and Congestion acceptable for the over-the-counter Allegra combination products on October 29, 2010, in OSE RCM Review #2010-1056 and 2010-1057.

1.3 PRODUCT INFORMATION

The Allegra product line is currently approved under prescription status. All Allegra products contain fexofenadine HCl as an active ingredient. Two Allegra products (Allegra-D and Allegra-D 24 Hour) contain pseudoephedrine HCl in addition to fexofenadine HCl. Allegra products containing single active ingredient (Fexofenadine) are approved for treatment of seasonal allergic rhinitis and chronic idiopathic urticaria.

The Applicant proposes the following six names for the Allegra over-the-counter line of products: Allegra Allergy, Allegra Hives, Children's Allegra Allergy, Children's Allegra Hives, Allegra-D 12 Hour Allergy and Congestion, and Allegra-D 24 Hour Allergy. Because the Children's products will contain multiple dosage forms (tablets, orally-disintegrating tablets, and oral suspension), the six proprietary names will cover ten total products. The ten products are listed below in Table 2.

Table 2: Proposed Non-prescription Allegra Product Line Information

Allegra, Children's Allegra, and Allegra-D			
Product	**Uses**	**Strength/Dosage Form**	**Dose**
Allegra Allergy (Fexofenadine HCl)	Relief of sneezing, runny nose, itchy, watery eyes, itchy nose or throat due to allergies	60 mg and 180 mg tablets	Adults and children >12 yo: 60 mg caplet: 1 tablet every 12 hours 180 mg caplet: 1 tablet every 24 hours Children <12 yo: Ask a doctor
Allegra Hives (Fexofenadine HCl)	Reduces hives and relives itching due to hives (urticaria). The product will not prevent hives or an allergic skin reaction from occurring	60 mg and 180 mg tablets	Adults and children >12 yo: 60 mg caplet: 1 tablet every 12 hours 180 mg caplet: 1 tablet every 24 hours Children <12 yo: Ask a doctor
Children's Allegra Allergy (Fexofenadine HCl)	Relief of sneezing, runny nose, itchy, watery eyes, itchy nose or throat due to allergies	30 mg tablets	Adults and Children > 12yo: 2 tablets every 12 hours Children 6 yo - 12 yo: 1 tablet every 12 hours Children < 6 yo: Ask a doctor
		30 mg orally disintegrating tablets,	Adults and Children > 12yo: 2 tablets every 12 hours Children 6 yo - 12 yo: 1 tablet every 12 hours Children < 6 yo: Ask a doctor
		30 mg/5 mL oral suspension	Adults and Children >12 yo: 2 teaspoonfuls every 12 hours Children 2yo - 12 yo: 1 teaspoonful every 12 hours Children <2 yo: Ask a doctor

Children's Allegra Hives (Fexofenadine HCl)	Reduces hives and relives itching due to hives (urticaria). The product will not prevent hives or an allergic skin reaction from occurring	30 mg tablets 30 mg orally disintegrating tablets, 30 mg/5 mL oral suspension	Adults and Children > 12yo: 2 tablets every 12 hours Children 6 - 12 yo: 1 tablet every 12 hours Children < 6 yo: Ask a doctor Adults and Children > 12yo: 2 tablets every 12 hours Children 6 yo - 12 yo: 1 tablet every 12 hours Children < 6 yo: Ask a doctor Adults and Children >12 yo: 2 teaspoonfuls every 12 hours Children 6yo - 12 yo: 1 teaspoonful every 12 hours Children < 6yo: Ask a doctor
Allegra-D 12 Hour Allergy and Congestion (Fexofenadine HCl and Pseudoephedrine HCl)	Relief of nasal congestion, sinus congestion and pressure, sneezing, runny nose, itchy and watery eyes, itchy nose or throat due to allergies	Fexofenadine HCl 60 mg and Pseudoephedrine HCl 120 mg tablets	Adults and Children >12 yo: 1 caplet ever 12 hours Children <12 yo: Ask a doctor
Allegra-D 24 Hour Allergy and Congestion (Fexofenadine HCl and Pseudoephedrine HCl)	Relief of nasal congestion, sinus congestion and pressure, sneezing, runny nose, itchy and watery eyes, itchy nose or throat due to allergies	Fexofenadine HCl 180 mg and Pseudoephedrine HCl 240 mg tablets	Adults and Children >12 yo: 1 tablet every 24 hours Children <12 yo: Ask a doctor

2 METHODS AND MATERIALS

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

2.1 SEARCH CRITERIA

For this review particular consideration was given to drug names beginning with the letter 'A' when searching to identify potentially similar drug root names, as 75% of the confused drug name reported by the ISMP Medication Error Reporting Program involve pairs beginning with the same letter.[1,2] When evaluating each proprietary name for confusion, both, the root name Allegra as well as each of the modifiers attached to the root name were analyzed.

[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)

DMEPA evaluated the appropriateness of the modifiers "Allergy", "Hives", and "Children's" for proposed non-prescription Allegra product line by searching commonly used databases (See Section 6) for currently marketed products that include above-named modifiers.

Because omission of a modifier (e.g., Allergy or Hives) is cited in literature as a common cause of medication error, DMEPA also considers the existing root name "Allegra" without modifiers as well as the proposed names Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives as complete names. [3] In addition, we note there are currently marketed prescription products with the root name "Allegra" (See Section 1.3.)

To identify drug names that may look or sound similar to the four proposed non-prescription Allegra product line proprietary names DMEPA considers the orthographic appearance of the root name Allegra and the modifiers on lined and unlined orders.

2.1.1 Search Criteria for "Allegra"

Specific attributes taken into consideration to identify drug names that may look similar to the root name Allegra include the length of the name Allegra (seven letters), upstrokes (three, capital 'A' and two lower case letters 'l'), down strokes (one, lower case 'g'), cross strokes (none), and dotted letters (none.)

When searching to identify potential names that may sound similar to the root name Allegra, the DMEPA searches for names with similar syllables (three), stresses (al-LE-gra) and placement of vowel and consonant sounds.

2.1.2 Search Criteria for "Allergy"

Specific attributes taken into consideration to identify drug names that may look similar to the modifier "Allergy" include the length of this modifier (seven letters), upstrokes (three, capital 'A' and two lower case letters 'l'), down strokes (two, lower case letters 'g' and 'y'), cross strokes (none), and dotted letters (none).

When searching to identify potential names that may sound similar to the modifier '"Allergy", the DMEPA searches for names with similar syllables (three), stresses (al-LER-gy, al-ler-GY) and placement of vowel and consonant sounds.

2.1.3 Search Criteria for "Hives"

Specific attributes taken into consideration to identify drug names that may look similar to the modifier "Hives" include the length of this modifier (five letters), upstrokes (one, capital 'H'), down strokes (none), cross strokes (one, Capital 'H'), and dotted letters (lower case 'i').

When searching to identify potential names that may sound similar to the modifier '"Hives", the DMEPA searches for names with similar syllables (one), stresses (HI-ves) and placement of vowel and consonant sounds.

2.1.4 Search Criteria for "Children's"

Specific attributes taken into consideration to identify drug names that may look similar to the modifier "Children's" include the length of this modifier (nine letters), upstrokes (four, capital 'C', lower case 'h', 'l', 'd'), down strokes (none), cross strokes (none), and dotted letters (two, lower case 'i' and apostrophe).

When searching to identify potential names that may sound similar to the modifier '"Children's", the DMEPA searches for names with similar syllables (two), stresses (CHIL-dren's) and placement of vowel and consonant sounds.

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[3] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. *J Gen Intern Med.* 2002; 17(8): 579-587.

2.2 FDA PRESCRIPTION ANALYSIS STUDIES

In order to evaluate the potential for misinterpretation of the proposed proprietary names in handwriting and verbal communication of the names, the following inpatient medication orders, outpatient, and verbal prescriptions were communicated during the FDA prescription studies (See Appendix C for images and complete information):

Figure 1: Allegra Allergy study samples

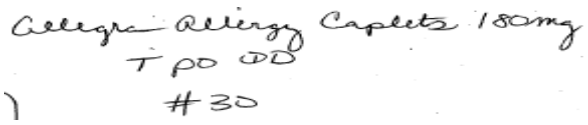
HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient prescription from 05/20/2010: 	Allegra Allergy Tablets 180 mg Take 1 by mouth daily #30

Figure 2: Children's Allegra Allergy study samples

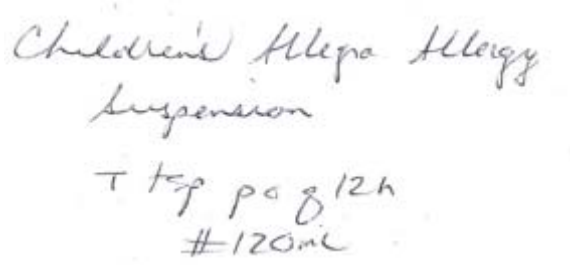
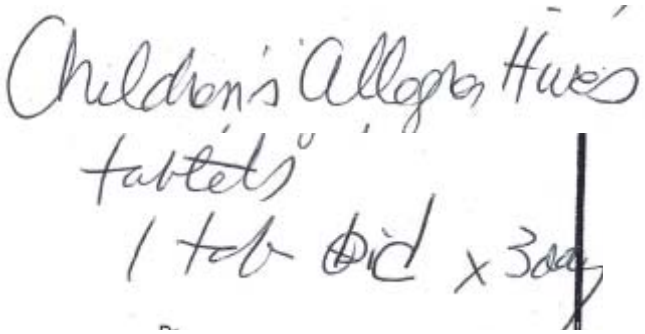
HANDWRITTEN REQUISITION MEDICATION ORDER
Outpatient prescription from 06/03/2010: 

Figure 3: Allegra Hives study samples

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order from 06/03/2010: 	Allegra Hives tablets 60 mg 1 po q 12 h

Figure 4: Children's Allegra Hives Tablets

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient prescription from 05/27/2010: 	Children's Allegra hives tablets 1 po bid for 3 days, #6

2.3 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

Since the root name Allegra and the proposed modifiers are currently marketed in the United States, DMEPA conducted a search of the AERS database to evaluate if confusion has occurred with the root name Allegra or any of the modifiers. To determine if the modifiers were involved in medication errors, we expanded our search to include Claritin and Zyrtec products lines.

The non-prescription Claritin product line is marketed containing the root name, "Claritin," and similar modifiers ("Allergy," "Hives Relief, and "Children's") to the proposed over-the-counter Allegra product line. Claritin is also an OTC non-sedating antihistamine that was originally marketed only as a prescription product. Thus, any medication errors associated with the use of Claritin's modifiers may be indicative of the medication errors that may occur due to the use of similar modifiers "Allergy", "Hives", and "Children's" of the non-prescription Allegra line once marketed.

The non-prescription Zyrtec product line also is marketed containing the root name, "Zyrtec," and similar modifiers ("Allergy," "Hives Relief, and "Children's") to the proposed over-the-counter Allegra product line. Zyrtec is also an OTC non-sedating antihistamine that was originally marketed only as a prescription product. Thus, any medication errors associated with the use of Zyrtec's similar modifier may be indicative of the medication errors that may occur due to the use of "Allergy," "Hives Relief, and "Children's" of the non-prescription Allegra line once marketed.

The reports identified through the FDA Adverse Event Reporting System (AERS) database were manually reviewed to group duplicate reports into cases and to determine if medication errors occurred. Those cases that did not describe a medication error were excluded from further analysis. For cases describing a medication error, we reviewed the cases to identify factors that contributed to the errors, and to ascertain if these risks might apply to the proposed proprietary names Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives. The search criteria are described below.

DMEPA also requested that Schering-Plough and McNeil submit data from the Safety Database and the Consumer Call Center regarding medication errors involving confusion between Claritin Hives Relief and Claritin Allergy products with dates ranging between April 1, 2006 and November 30, 2010 and between Zyrtec Hives Relief and Zyrtec Allergy products with dates ranging between January 1, 2008 and July 30, 2010.

2.3.1 Allegra Product Line Medication Error Search Criteria

The Adverse Event Reporting System (AERS) database search conducted on May 24, 2010 used the following criteria: MedDRA high level group term (HLGT) "Medication Errors" and "Product Quality Issues" as well as high level terms (HLT) "Maladministrations", "Medication Errors NEC", and "Product Quality Issues NEC" along with the trade name Allegra and verbatim "Allegr%". The search was limited to the timeframe of May 12, 2003 to May 24, 2010 because DMEPA had conducted an AERS search previously through May 12, 2003 identifying medication errors associated with existing Allegra products for OSE RCM review #05-0179 completed on August 23, 2005.

2.3.2 Claritin Product Line Medication Error Search Criteria

The AERS database search conducted on May 24, 2010 used the following criteria: MedDRA high level group terms (HLGT) "Medication Errors" and "Product Quality Issues" as well as high level terms (HLT) "Maladministrations", "Medication Errors NEC", and "Product Quality Issues NEC" along with a trade name Claritin and verbatim "Clari%". The search was limited to the dates of May 1, 2006 to May 24, 2010 because DMEPA conducted a medication error search involving Claritin product line previously in OSE RCM review #06-0013 completed on May 23, 2006.

2.3.3 Zyrtec Product Line Medication Error Search Criteria

The AERS database search conducted on May 24, 2010 used the following criteria: MedDRA high level group terms (HLGT) "Medication Errors" and "Product Quality Issues" as well as high level terms (HLT) "Maladministrations", "Medication Errors NEC", and "Product Quality Issues NEC" along with a trade name Zyrtec and verbatim "Zyrt%". The search was limited to the dates of June 12, 2007 to May 24, 2010 because a medication error search for the Zyrtec product line was conducted previously in OSE RCM Review # 007-400, 2007-402, 2007-403, 2007-404, 2007-405, 2007-406, and 2007-407 completed on November 7, 2007.

3 RESULTS

The following Sections describe the findings of database and information sources searches, FDA prescription studies, expert panel discussions, as well as our AERS, Schering-Plough, and McNeil Pharmacovigilance databases searches.

3.1 DATABASE AND INFORMATION SOURCES

The DMEPA Safety Evaluator searches yielded a total of a twenty-one names (n=21) as having some similarity to the names Allegra Allergy, Allegra Hives, Children's Allegra Allergy, and Children's Allegra Hives.

Three names of the 21 were thought to look like the root name Allegra by the Safety Evaluator. These include Aldara, Alora, and Kaletra. The remaining eighteen names were thought to look like and sound like the proposed non-prescription Allegra line names by the DMEPA's Safety Evaluator. These include Advil Allergy Sinus, Children's Advil, Children's Advil Allergy Sinus, Benadryl Allergy, Children's Benadryl, Claritin-D 12 Hour, Claritin-D 24 Hours, Children's Claritin, Claritin Hives Relief, Claritin Reditabs Hives Relief, Pediacare Children's Allergy, Tylenol Children's Allergy, Tavist Allergy, Zyrtec Allergy, Zyrtec Hives Relief, Children's Zyrtec Hives Relief **,** Children's Zyrtec Allergy, and Zyrtec-D Allergy & Congestion.

Additionally, DMEPA staff did not identify any United States Adopted Names (USAN) stems in the proposed proprietary names, as of May 20, 2010.

3.2 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 the root name Allegra, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, or Children's Allegra Hives.

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

3.3 FDA PRESCRIPTION ANALYSIS STUDIES

A total 83 practitioners responded to the six FDA Prescription Analysis studies.

3.3.1 Allegra Allergy Prescription Studies

Twenty-three practitioners responded to the prescription analysis studies involving Allegra Allergy. Twenty-one respondents interpreted this proposed name correctly as 'Allegra Allergy', with correct interpretation occurring with outpatient prescriptions (n=14) and voice prescription studies (n=7). The remaining two participants omitted the modifier "Allergy" and interpreted the proposed name as 'Allegra.' See Appendix See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.3.2 Children's Allegra Allergy Prescription Studies

Thirteen practitioners responded to the prescription analysis studies involving Children's Allegra Allergy. All 13 respondents interpreted this proposed name correctly as 'Children's Allegra Allergy', with correct interpretation occurring with outpatient prescriptions (n=7) and voice prescription studies (n=6). See Appendix See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.3.3 Allegra Hives Prescription Studies

Twenty-four practitioners responded to the prescription analysis studies involving Allegra Hives. Eleven respondents interpreted this proposed name correctly as 'Allegra Hives', with correct interpretation occurring with inpatient orders (n=11). Two participants omitted the modifier and interpreted the proposed name as 'Allegra' (n=2). See Appendix See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.3.4 Children's Allegra Hives Prescription Studies

Twenty-three practitioners responded to the prescription analysis studies involving Children's Allegra Hives. Fifteen respondents interpreted this proposed name correctly as 'Children's Allegra Hives', with correct interpretation occurring with outpatient prescriptions (n=7) and voice prescription studies (n=8). The remaining eight participants omitted part of the modifier or misinterpreted the modifier of the proposed name. Those participants responded with 'Children's Allegra' (n=4), "Children's Allegra Hive' (n=2), 'Children's Allergen Hives" (n=1), and Children's Allergy (n=1). See Appendix See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

3.4 FDA ADVERSE EVENT REPORTING SYSTEM (AERS) DATABASE

3.4.1 Allegra Medication Error Cases

DMEPA retrieved a total of thirty nine reports (n=39) from the FDA Adverse Event Reporting System (AERS) database associated with the currently marketed Allegra product line. After grouping duplicate reports into cases and eliminating cases not pertaining to confusion between Allegra products within Allegra product line or Allegra products and another drug product, two cases remained. Both cases were associated with the placement of the wrong drug product (Glucovance or Atenolol) into Allegra prescription bottles during the dispensing process due to similarity in tablets' size, shape, and color. In the Glucovance case (ISR #5210269-1), the reporter (pharmacist) stated that error occurred due to the similarity in tablets' size, shape, and color. This error does not appear to be related to name confusion. In the Atenolol case (ISR #5295918-4), the reporter (also pharmacist) was not able to identify the source of the confusion between Atenolol and Allegra (See Appendix G for the narrative summary of cases.) Since name confusion could not be ruled out as a contributing factor to confusion, DMEPA included this name in our evaluation of look-alike and sound-alike names.

3.4.2 Claritin Medication Error Cases

DMEPA retrieved a total of forty eight reports (n=48) from the AERS database involving the Claritin product line. However, after grouping duplicate reports into cases and eliminating cases not pertaining to confusion between the modifiers "Allergy", "Hives" and "Children's" of Claritin products or confusion of Claritin products and another drug product containing similar modifiers, no relevant cases remained.

However, Schering-Plough submitted the requested information from Pharmacovigilance and Consumer Information Databases regarding medication errors involving confusion between Claritin Allergy and Claritin Hives Relief products to the FDA on August 12, 2010. The Sponsor reported three cases (n=3) of confusion between April, 2006 and November, 2008. All three cases reported purchasing of Claritin Hives Relief instead of Claritin Allergy product. Patient outcome was not reported. Although not enough details in cases were provided to identify the root cause of the error, we can infer that this error occurred due to the due to the confusing nomenclature and insufficient differentiation in the labeling.

3.4.3 Zyrtec Medication Error Cases

DMEPA retrieved a total of two hundred and forty one reports (n=241) from the AERS database associated with the Zyrtec product line. After grouping duplicate reports into cases and eliminating cases not pertaining to confusion between the modifiers of OTC Zyrtec products as well as packaging similarity or confusion of Zyrtec products and another drug product containing similar modifiers, one relevant case remained (n=1, ISR #5798449-8). This medication error case involved mix-up of two Zyrtec products due to confusion of the modifiers. The reporter stated that her pediatrician instructed her to buy Zyrtec Allergy for a 20-month-old child. However, the consumer became confused and bought Zyrtec Hives instead. Although the consumer acknowledged that the error may not have "mattered" given that both "Hives Relief" and "Allergy" products had the same active ingredient and concentration, the consumer was upset and anxious when she later discovered that the labeling for Zyrtec Hives states the product is inappropriate for children under 6 years of age (See Appendix I for the complete narrative of the case). It appears from this case that both nomenclature and labeling contributed to this medication error.

Additionally, McNeil submitted requested information from the Pharmacovigilance and Consumer Information Databases regarding medication errors involving confusion between Zyrtec Hives Relief and Zyrtec Allergy products to the FDA on August 5, 2010. The Sponsor reported that during the time period between January 1, 2008 and July 30, 2010 fifty four medication error cases (n=54) involving confusion between Children's Zyrtec Hives Relief and Children's Zyrtec Allergy have occurred. Two cases (n=2, AER #2008054103 and AER #2009000760) reported administration of Children's Zyrtec Hives Relief instead of Children's Zyrtec Allergy to a 19 month old and a 15 month old children respectively. The doses were not specified in the reports. The remaining fifty-two cases (n=52) reported confusion between Children's Zyrtec Hives Relief and Children's Zyrtec Allergy. These cases stated that the product was not administered at the time of reporting. Forty three case (n=43) reported purchase of Children's Zyrtec Hives Relief instead of Children's Zyrtec Allergy. Two cases (n=2) reported purchase of Children's Zyrtec Allergy instead of Children's Zyrtec Hives Relief. Four cases (n=4) described customers that were in a process of purchasing one of the Children's Zyrtec product, but were confused due to the different modifiers, but identical active ingredients. The remaining three cases (n=3) did not specify which product they had, just stated the confusion. McNeil reported that none of the fifty-four cases (n=54) resulted in patient harm.

Although no specific details in the cases were provided to identify the precise root cause of the error, we can suspect that this error occurred due to the confusing nomenclature (i.e. shared root names and presence of the modifiers) and insufficient differentiation in the labeling of the products. Thus, since all of the OTC Allegra product will share the root name and contain similar modifiers to Claritin's product line (e.g., Allergy and Hives), it is important to achieve sufficient differentiation among the products through labeling.

We also note that McNeil has since discontinued marketing products containing the modifier "Hives relief" such as Children's Zyrtec Hives Relief from the market. No additional cases of confusion between the labeling of Zyrtec products containing various modifiers were reported.

3.5 COMMENTS FROM DIVISION OF NON-PRESCRIPTION CLINICAL EVALUATION

On July 9, 2010 and July 21, 2010 DMEPA notified DNCE that we find the names Allegra Allergy and Children's Allegra Allergy acceptable. DNCE concurred with DMEPA's assessment.

Additionally, after further discussions and negotiations, DMEPA and DNCE reached an agreement that the name Allegra Hives is acceptable during the meeting on November 23, 2010 contingent upon the fact that the indications for the product in the *Use Section* of the Drug Pacts Panel remains unchanged for the proposed indication stated in the May 14, 2010 proprietary name submission.

3.6 SAFETY EVALUATOR RISK ASSESSMENT OF PROPOSED PROPRIETARY NAME

Independent searches conducted by the DMEPA safety evaluator assigned to this review resulted in the identification of three additional names. One name, Atenolol, was identified in the AERS database searches. The two other names were Actigall and Viagra were identified during previous AERS search for the root name Allegra for the prescription product.

Therefore, a total of twenty four names (n=24) were considered for their potential similarity to the four proposed names Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives. Nineteen (n=19) of the twenty-four names were not evaluated further for the following reasons: Fifteen names (n=15) lacked orthographic and/or phonetic similarity the proposed non-prescription Allegra product line names and four names (n=4) have been discontinued by the sponsors (See Appendix D and Appendix E.)

Failure mode and effect analysis (FMEA) was then applied to determine if the proposed proprietary names could potentially be confused with the remaining five names (n=5) and lead to medication errors. This analysis determined that the name similarity the six proposed product names and these five products was unlikely to result in medication errors for the reasons presented in Appendices F through H.

4 DISCUSSION

The proposed proprietary names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives were evaluated from a safety and promotional perspective. Furthermore, input from pertinent disciples involved with the review of this application are considered accordingly.

4.1 PROMOTIONAL ASSESSMENT

DDMAC did not find the names Allegra Allergy, Children's Allegra Allergy, Allegra Hives, or Children's Allegra Hives promotional.

4.2 SAFETY ASSESSMENT

4.2.1 Prescription Studies

The majority of misinterpretation of the prescription studies involved partial omission of the modifiers. However, we believe that using unique names for each product increases the risk of concomitant therapy. Thus, we believe that proposed naming convention of using the root name with modifier is preferable to using a unique name.

4.2.2 Root name Allegra

Although there were medication error cases involving confusion between the root name Allegra and Atenolol identified in the Adverse Event Reporting System (AERS) database search, we believe that the confusion between these names and the proposed OTC product line will be reduced because of the modifiers and differences in product characteristics (See Appendices F and G).

4.2.3 Modifiers

DMEPA finds the four proposed proprietary names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives suitable for use with this product line.

4.2.3.1 Modifier "Allergy"

DMEPA finds the modifier "Allergy" suitable for the use with the root name Allegra because this modifier is present across the four proprietary names in the OTC Allegra product line, except Allegra Hives and Children's Allegra Hives. Thus, the modifier "Allergy" implies similar use of the OTC Allegra products. Additionally, the modifier "Allergy" also carries consistent meaning with other marketed OTC non-sedative antihistamines, Claritin and Zyrtec. However, total of fifty-five cases (n=55) of confusion was identified between the modifiers "Allergy" and "Hives Relief" (See Appendices I and J). Thus, if Allegra Allergy and Allegra Hives will co-exist on the market, the labels and labeling of these products should be well differentiated to reduce the risk of the medication error occurrence (See the forthcoming labeling OSE-RCM review #2010-1112, 2010-1115, 2010-1116, 2010-1117, 2010-1120, 2010-1121).

4.2.3.2 Modifier "Hives"

DMEPA finds the modifier "Hives" suitable for the use with the root name Allegra. This modifier implies that the product reduces hives and relieves itching due to hives. DMEPA was initially concerned that modifier 'Hives' may be misleading if the *Use Section* of this non-sedating antihistamine was consistent with other non-sedating antihistamines (Claritin and Zyrtec) because the *Use Section* for those products stated that the product relieves itching due to hives. However, DNCE anticipates allowing the Applicant claim both of these indications in the *Use Section* of the Drug Facts Panel as stated as a meeting between DMEPA and DNCE on November 23, 2010. In response to the mid-cycle email from DMEPA as well as through labeling negotiation meeting held on November 23, 2010, DNCE stated that "*The drug relieves hives and has clinical data to support its efficacy"*.

However, although the modifier "Hives" is acceptable from the promotional perspective, DMEPA has identified post marketing cases of confusion between similar modifiers "Allergy" and "Hives Relief" with Claritin and Zyrtec product line. Thus, if Allegra Allergy and Allegra Hives will co-exist on the market, the labels and labeling of these products should be well differentiated to reduce the risk of the medication error occurrence (See the forthcoming labeling OSE-RCM review #2010-1112, 2010-1115, 2010-1116, 2010-1117, 2010-1120, 2010-1121).

4.2.3.3 Modifier "Children's"

DMEPA finds the modifier "Children's" is not vulnerable to confusion with another modifier. The modifier "Children's" has been used consistently among various over-the-counter products to identify the pediatric population. We recommend that the labels and labeling of these products clearly state the appropriate ages for these products (The forthcoming labeling OSE-RCM review #2010-1112, 2010-1115, 2010-1116, 2010-1117, 2010-1120, 2010-1121).

5 CONCLUSIONS AND RECOMMENDATIONS

Our findings of the Proprietary Name Risk Assessment indicate that the four proposed proprietary names, Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives are acceptable. We note that the proposed proprietary names Allegra Hives and Children's Allegra Hives are conditionally acceptable contingent upon the fact that the indications for the product in the *Use Section* of the Drug Pacts Panel remain unchanged.

DMEPA considers this review final. However, if any of the proposed products' characteristics as stated in this review are altered prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name(s) must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name(s) on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change.

If you have further questions or need clarifications, please contact Janet Anderson, OSE Project Manager, at (301) 796-0675.

5.1 COMMENTS TO THE APPLICANT

We have completed our review of the four proprietary names Allegra Allergy, Children's Allegra Allergy, Allegra Hives, and Children's Allegra Hives. We have concluded that these four names are acceptable.

If any of the proposed products' characteristics are altered (e.g., indications) prior to approval of the product, DMEPA rescinds this Risk Assessment finding and the name(s) must be resubmitted for review. In the event that our Risk Assessment finding is rescinded, the evaluation of the name(s) on resubmission is independent of the previous Risk Assessment, and as such, the conclusions on re-review of the name are subject to change. If we find the names unacceptable following the re-review, we will notify you.

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. The Document Archiving, Reporting, and Regulatory Tracking System (DARRTS)

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

5. Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

6. Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)

Drugs@FDA contains most of the drug products approved since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA approved brand name, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and "Chemical Type 6" approvals.

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

The FDA Orange Book provides a compilation of approved drug products with therapeutic equivalence evaluations.

8. U.S. Patent and Trademark Office (http://www.uspto.gov)

USPTO provides information regarding patent and trademarks.

9. Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

10. Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)

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

11. Natural Medicines Comprehensive Databases (www.naturaldatabase.com)

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

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

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

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

USAN Stems List contains all the recognized USAN stems.

14. Red Book Pharmacy's Fundamental Reference

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

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

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

16. Medical Abbreviations Book

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

17. Dallas, Scott OSE Review #03-0205, Claritin Hives Relief and Claritin Reditabs Hives Relief Proprietary Names Review

18. Duffy, Felicia OSE Review #2007-400, 2007-402, 2007-403, 2007-404, 2007-405, 2007-406, 2007-407 Zyrtec Allergy, Zyrtec Hives, Children's Zyrtec Allergy, Children's Zyrtec Hives, and Zyrtec-D Allergy and Congestion Proprietary Names review

19. Pincock, Laura OSE Review #05-0179 Allegra Suspension Proprietary Name Review

APPENDICES

Appendix A:

FDA's Proprietary Name Risk Assessment considers the potential for confusion between the proposed proprietary name and the proprietary and established names of drug products existing in the marketplace and those pending IND, NDA, BLA, and ANDA products currently under review by the Center. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

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. [5] DMEPA uses FMEA to analyze whether the drug names identified with orthographic or phonetic similarity to the proposed proprietary name could cause confusion that subsequently leads to medication errors in the clinical setting. DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product.

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

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. Because drug name confusion can occur at any point in the medication use process, DMEPA staff considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[6] DMEPA provides the product characteristics considered for this review in section one.

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

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

[6] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

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 Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice.

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

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

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

1. Database and Information Sources

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

2. CDER Expert Panel Discussion

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

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

3. FDA Prescription Analysis Studies

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

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

4. 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.[7] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

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

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

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

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

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

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

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice

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

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 Sponsor 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 Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Sponsor. 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 Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage

strategies, such as drug name changes, in the past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval. . (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 Sponsor 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 Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

Appendix B: Letters with possible orthographic or phonetic misinterpretation

Letters in the Root Name Allegra	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'A'	'ce', 'FL', 'H', 's', 'o'	Any vowel
Lower case 'a'	'el', 'd', 'o'	Any vowel
Lower case 'l'	'b', 'e', 's', 'A', 'P', 'i'	
Lower case 'e'	'a', 'i', 'l', 'p'	Any vowel
Lower case 'g'	'q', 'j', 's'	'k', 'j'
Lower case 'r'	'c', 'e', 'n', 's', 't', 'x', 'z'	

Letters in the modifier "Allergy"	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'A'	'ce', 'FL', 'H', 's'	Any vowel
Lower case 'a'	'el', 'd', 'o'	Any vowel
Lower case 'l'	'b', 'e', 's', 'A', 'P', 'i'	
Lower case 'e'	'a', 'i', 'l', or 'p'	Any vowel
Lower case 'r'	'c', 'e', 'n', 's', 't', 'x', 'z'	
Lower case 'g'	'q', 'j', 's'	'k', 'j'
Lower case 'y'	'f', 'p', 'u', 'v', 'x', 'Z'	'e', 'i', 'u'

Letters in the modifier "Hives"	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'H'	'FL'	
Lower case 'h'	'k', 'b', 'n', 'L', 'Z'	
Lower case 'i'	'e'	'y', 'e'
Lower case 'v'	'r', 'u', 'y', 'z', 'x'	'f'
Lower case 'e'	'a', 'i', 'l', 'p'	Any vowel
Lower case 's'	'G', 'g', 'n', 'c', 'z', '5'	'x', 'z'

Letters in the modifier Children's	**Scripted may appear as**	**Spoken may be interpreted as**
Capital 'C'	'L', 'Z'	'k', 'z'
Lower case 'c'	'a', 'e', 'I', 'l', 'z'	'k', 'z'
Lower case 'h'	'k', 'b', 'n', 'L', 'Z'	
Lower case 'i'	'e'	'y', 'e'
Lower case 'l'	'b', 'e', 's', 'A', 'P', 'i'	
Lower case 'd'	'cl', 'a'	't', 'b'
Lower case 'r'	'c', 'e', 'n', 's', 't', 'x', 'z'	
Lower case 'e'	'a', 'i', 'l', 'p'	Any vowel
Lower case 'n'	'm', 'u', 'x', 'r', 'h', 's'	'm', 'dn', 'kn', 'mn, 'pn'
Lower case 's'	'G', 'g', 'n', 'c', 'z', '5'	'x', 'z'

Appendix C: FDA Prescription study for Allegra OTC products

Figure 1: Allegra Allergy study samples

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient prescription from 05/20/2010: Allegra Allergy Caplets 180mg T po QD #30	Allegra Allergy Tablets 180 mg Take 1 by mouth daily #30

Table 1: Responses to prescription study

Outpatient Prescription 05/20/2010: Allegra Allergy	Voice Prescription 05/20/2010: Allegra Allergy
Allegra Allergy	Allegra
Allegra Allergy	Allegra Allergy
Allegra Allergy	Allegra Allergy
Allegra Allergy	Allegra Allergy
Allegra	Allegra Allergy
Allegra Allergy	Allegra Allergy
Allegra Allergy	Allegra Allergy
Allegra Allergy	Allegra Allergy
Allegra Allergy	
Allegra Allergy	
Allegra Allergy	
Allergic Allergy	
Allegra Allergy	
Allegra Allergy	
Allegra Allergy	

Figure 2: Children's Allegra Allergy study samples

HANDWRITTEN REQUISITION MEDICATION ORDER

Outpatient prescription from 06/03/2010:

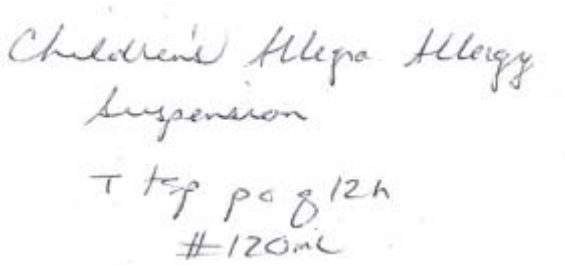


Table 2: Responses to prescription study

Outpatient Prescription 06/03/2010:	**Outpatient Prescription 06/03/2010:**
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	Children's Allegra Allergy
Children's Allegra Allergy	

Figure 3: Children's Allegra Hives Tablets

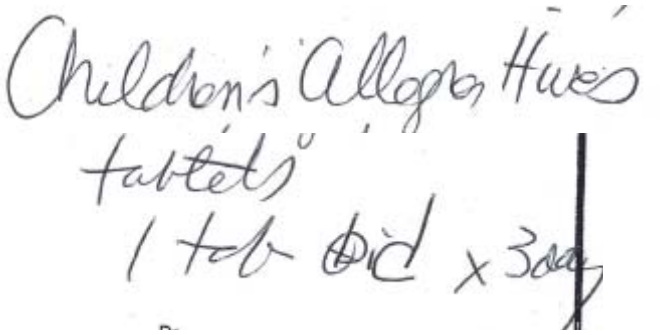
HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Outpatient prescription from 05/27/2010: 	Children's Allegra hives tablets 1 po bid for 3 days, #6

Table 3: Responses to prescription study

Outpatient Prescription 05/27/2010	Voice Prescription 05/27/2010:
Children's Allegra Hives	Children's Allegra Hives
Children's Allegra Hives	Children's Allegra Hives
Children's Allegra Hives	Children's Allegra
Children's Allergy	Children's Allegra Hives
Children's Allegra Hives	Children's Allegra Hives
Children's Allegra Hives	Children's Allegra
Children's Allegra Hives	Children's Allegra
Children's Allergy Hives	Children's Allegra Hives
Children's Allergen Hives	Children's Allegra Hives
	Children's Allegra
	Children's Allegra Hives
	Children's Allegra Hive
	Children's Allegra Hives
	Children's Allegra Hive

Figure 4: Allegra Hives study samples

HANDWRITTEN REQUISITION MEDICATION ORDER	VERBAL PRESCRIPTION
Medication Order from 06/03/2010: 	Allegra Hives tablets 60 mg 1 po q 12 h

Table 4: Responses to prescription study

Medication Order 06/03/2010:	Voice Prescription 06/03/2010
Allegra Hives	Allegra
Allegra Hives	Allegra Hive
Allegra Hives	Allegra Hive
Allegra Hives	Allegra Hive
Allegra Hives	Allegra Hive
Allegra Hives	Allegra Hive
Allegra Hives	Allegra (high)
Allegra	Allegra HI
Allegra	Allegra Hive
Allegra Hives	Allegra Hi
Allegra Hives	
Allegra Hives	
Leggra hives	
Allegra Hives	

Appendix D: Names of products that lack convincing orthographic and/or phonetic similarity

Drug Product Name	Drug Product Name
Advil Allergy Sinus	Kaletra
Children's Advil	Pediacare Children's Allergy
Children's Advil Allergy Sinus	Tylenol Children's Allergy
Benadryl Allergy	Tavist Allergy
Children's Benadryl	Zyrtec Allergy
Claritin-D 12 Hour	Children's Zyrtec Allergy
Claritin-D 24 Hour	Zyrtec-D Allergy & Congestion
Children's Claritin	

Appendix E: Names of products withdrawn from the market or not marketed in the U.S without a generic equivalent.

Proprietary Name	Similarity to proposed OTC Allegra product names	Status
Claritin Hives Relief	Look alike and sound alike	Product discontinued with no therapeutic equivalents available. This product was previously marketed for relief of itching due to hives
Claritin Reditabs Hives Relief	Look alike and sound alike	Product discontinued with no therapeutic equivalents available. This product was previously marketed for relief of itching due to hives
Zyrtec Hives Relief	Look alike and sound alike	Product discontinued with no therapeutic equivalents available. This product was previously marketed for relief of itching due to hives
Children's Zyrtec Hives Relief	Look alike and sound alike	Product discontinued with no therapeutic equivalents available. This product was previously marketed for relief of itching due to hives

Appendix F: Products with no overlap in strength or dose

Product name with potential for confusion	Similarity to proposed OTC Allegra products	Strength	Usual Dosage (If applicable)
Allegra Allergy **(Fexofenadine HCl)**	**N/A**	**Tablets:** **60 mg, 180 mg**	**<u>Adults and children >12 yo</u>:** **60 mg caplet: 1 caplet by mouth every 12 hours** **180 mg caplet: 1 caplet by mouth every 24 hours** **<u>Children <12 yo:</u>** **Ask a doctor**
Allegra Hives **(Fexofenadine HCl)**	**N/A**	**Tablets:** **60 mg, 180 mg**	**<u>Adults and children >12 yo</u>:** **60 mg caplet: 1 caplet by mouth every 12 hours** **180 mg caplet: 1 caplet by mouth every 24 hours** **<u>Children <12 yo:</u>** **Ask a doctor**
Children's Allegra Allergy **(Fexofenadine HCl)**	**N/A**	**Tablets, 30 mg** **Orally disintegrating tablets, 30 mg** **Oral suspension 30 mg/5 mL**	**<u>Tablets and Orally Disintegrating Tablets:</u>** **<u>Adults and Children > 12yo:</u>** **2 tablets by mouth every 12 hours** **<u>Children 6 yo - 12 yo:</u>** **1 tablet by mouth every 12 hours** **<u>Children < 6 yo</u>:** **Ask a doctor** ***<u>Oral Suspension</u>*** **<u>Adults and Children >12 yo:</u>** **2 teaspoonfuls by mouth every 12 hours** **<u>Children 2yo - 12 yo:</u>** **1 teaspoonful by mouth every 12 hours** **<u>Children <2 yo:</u>** **Ask a doctor**
Children's Allegra Hives **(Fexofenadine HCl)**	**N/A**	**Tablets, 30 mg** **Orally disintegrating tablets, 30 mg** **Oral suspension 30 mg/5 mL**	**<u>Adults and Children > 12yo:</u>** **2 tablets by mouth every 12 hours** **<u>Children 6 yo - 12 yo:</u>** **1 tablet by mouth every 12 hours** **<u>Children < 6 yo</u>:** **Ask a doctor**
Alora (Estradiol Extended Release)	Look alike	Transdermal System: 0.025 mg/24 hr, 0.05 mg/24 hr, 0.075 mg/24 hr, 0.1 mg/24 hr	Apply 1 patch to trunk or buttocks, replace twice weekly
Viagra (Sildenafil Citrate)	Sound alike	Tablets: 25 mg, 50 mg, 100 mg	Take 1 tablet by moth 1 hour prior to sexual activity, up to once daily

<u>Appendix G:</u> Single Strength Products but Differentiating Product Characteristics that Minimize the Risk of Medication Errors

Product name with potential for confusion	Similarity to proposed OTC Allegra products	Strength	Usual Dosage (If applicable)	Name confusion is prevented by the combination of stated product characteristics, orthographic, and/or phonetic differences as described
Allegra Allergy **(Fexofenadine HCl)**	**N/A**	**Tablets:** **60 mg, 180 mg**	**<u>Adults and children >12 yo</u>:** **60 mg caplet: 1 caplet by mouth every 12 hours** **180 mg caplet: 1 caplet by mouth every 24 hours** **<u>Children <12 yo:</u>** **Ask a doctor**	**N/A**
Allegra Hives **(Fexofenadine HCl)**	**N/A**	**Tablets:** **60 mg, 180 mg**	**<u>Adults and children >12 yo</u>:** **60 mg caplet: 1 caplet by mouth every 12 hours** **180 mg caplet: 1 caplet by mouth every 24 hours** **<u>Children <12 yo:</u>** **Ask a doctor**	**N/A**
Children's Allegra Allergy **(Fexofenadine HCl)**	**N/A**	**Tablets, 30 mg** **Orally disintegrating tablets, 30 mg** **Oral suspension 30 mg/5 mL**	**<u>Tablets and Orally Disintegrating Tablets:</u>** **<u>Adults and Children > 12yo:</u>** **2 tablets by mouth every 12 hours** **<u>Children 6 yo - 12 yo:</u>** **1 tablet by mouth every 12 hours** **<u>Children < 6 yo</u>:** **Ask a doctor** ***<u>Oral Suspension</u>*** **<u>Adults and Children >12 yo:</u>** **2 teaspoonfuls by mouth every 12 hours** **<u>Children 2yo - 12 yo:</u>** **1 teaspoonful by mouth every 12 hours** **<u>Children <2 yo:</u>** **Ask a doctor**	**N/A**
Children's Allegra Hives **(Fexofenadine HCl)**	**N/A**	**Tablets, 30 mg** **Orally disintegrating tablets, 30 mg** **Oral suspension 30 mg/5 mL**	**<u>Adults and Children > 12yo:</u>** **2 tablets by mouth every 12 hours** **<u>Children 6 yo - 12 yo:</u>** **1 tablet by mouth every 12 hours** **<u>Children < 6 yo</u>:** **Ask a doctor**	**N/A**

Actigall (Ursodial)	Look alike	Capsules: 300 mg	Depending on indication: 8mg/kg/day-20 mg/kg/day by mouth in one to four divided doses.	Orthographic The root name Allegra contains 7 letters vs. Actigall contains 8 letters. Allegra contains 3 upstroke immediately next to each other in the beginning of the name vs. Actigall contains 3 upstrokes in the beginning, middle and the end of the name. Additionally, the letter strings '-lle-' and '-ra' in Allegra are different with corresponding letter strings in Actigall Presence of the Modifiers OTC Allegra product line will contain modifiers as a part of the proprietary name vs. Actigall does not contain any modifiers associated with the name.
Aldara (Imiquimod)	Look alike	Topical cream: 5% (box of 12 packets)	Treatment of external genital and perianal warts: Apply a thin layer to affected area 3 times per week and leave on the skin for 6-10 hours Treatment of clinically typical, non-hyperkeratotic, non-hypertrophic actinic keratosis Apply a thin layer 2 times per week for 16 weeks to affected areas and leave on the skin for approximately 8 hours Treatment of clinically visible or palpable actinic keratosis Apply a thin layer once a day for 2 weeks before bedtime to affected areas and leave on the skin for approximately 8 hours, followed by a 2 week cycle of no treatment, then repeat. Treatment of superficial basal cell carcinoma Apply daily 5 times per week for 6 weeks before bedtime and leave on the skin for approximately 8 hours	Dosage Form Tablets, tablets, or oral suspension vs. cream Route of Administration Oral vs. topical Usual Dose 1 tablet or 5 mL vs. one application Frequency of Administration Once a day to twice a day vs. various (see usual dose column for Aldara) Presence of Modifiers and Modifiers Presence of modifiers and modifiers vs. no modifier

Atenolol	Look alike	Tablets: 25 mg, 50 mg, and 100 mg	Take 1 tablet orally once daily	Although confusion between prescription Allegra and Atenolol have occurred, the following product characteristics should help differentiate between Allegra OTC product line and Atenolol Orthographic Allegra contains 3 upstrokes next to each other and 1 downstroke vs. Atenolol contains 4 upstrokes throughout the name and no downstrokes. Additionally, the letter string '-legra' does not appear to the letter string '-enolol' when scripted. No Overlap in Strength Allegra is available in 30 mg, 60 mg, and 180 mg vs. Atenolol is available in 25 mg, 50 mg, and 100 mg Presence of the modifiers Allegra OTC product line contains different modifiers: 'Allergy', 'Hives , 'D-12 Hour Allergy and Congestion', and 'D-24 Hours Allergy and Congestion' whereas Atenolol does not
Viagra (Sildenafil Citrate)	Sound alike	Tablets: 25 mg, 50 mg, 100 mg	Take 1 tablet by moth 1 hour prior to sexual activity, up to once daily	Although confusion between prescription Allegra and Viagra have occurred, the following product characteristics should help differentiate between Allegra OTC product line and Atenolol No Overlap in Strength Allegra is available in 30 mg, 60 mg, and 180 mg vs. Viagra is available in 25 mg, 50 mg, and 100 mg Presence of the modifiers Allegra OTC product line contains different modifiers: 'Allergy', 'Hives , 'D-12 Hour Allergy and Congestion', and 'D-24 Hours Allergy and Congestion' whereas Viagra does not

Appendix H: Narratives of medication error cases involving confusion with currently marketed Allegra product line from AERS database searched from May 12, 2003 to May 24, 2010.

FDA Receipt Date/ ISR #	Type of Medication Error	Narrative	Patient Outcome
01/16/2007 5210269-1	Wrong drug was found in the prescription bottle-Glucovance	41 yo female patient was dispensed Glucovance tablets in pharmacy prescription bottle with the correctly affixed label for Allegra. Patient took the wrong medication from July 2006 until September 2006. Patient felt weak and dizzy the entire time. Lab tests at MD office showed severe hypoglycemia. When patient brought the bottle to the pharmacy, pharmacist explained that Allegra tablets and Glucovance tablets are stored together on the shelf and look very much alike (similar size, shape and color).	Patient experienced severe hypoglycemia for 2 months while taking the wrong medication.
04/10/2007 5295918-4	Wrong drug was found in the prescription bottle-Atenolol	A prescription was written for Allegra 60 mg, but the refill bottle contained Atenolol 25 mg instead of generic Fexofenadine. Pharmacist reporting the medication error stated that tablets do not look similar at all. He said he did not have explanation to why this error occurred.	Patient caught the error before administering a tablet and brought the bottle to the pharmacy

Appendix I: Narrative of pertinent medication error case with Zyrtec brand product line from AERS database from June 12, 2007 to May 26, 2010

FDA Receipt Date/ ISR #	Type of Medication Error	Narrative	Patient Outcome
07/01/2008 5798449-8	Wrong drug-names and labeling confusion between Children's Zyrtec Allergy and Children's Zyrtec Hives	Has anyone seen the new Zyrtec OTC products? Very confusing. Not sure what the real diff is between "hives" formulation and "allergy" but they are labeled differently. Could be confusing for consumers. I was given written instructions from pediatrician to give my 20 month old "1/2 tsp at bedtime." At first I grabbed the "hives" bottle but then saw it said for age 6 and up. For some reason, the age 2 "allergy" bottles were behind the pharmacy counter and not on the shelf. I think they are the same concentration so it may not have mattered. But it freaked me out. I contacted the manufacturer and asked if I bought hives by mistake (and commented that the boxes look so similar) could I still give it to my 2 year old if I gave the correct dose from the allergy box. Look-alike name confusion (both products being named Children's Zyrtec). Look-alike packaging. Two Childrens' Zyrtec products that contain the same ingredient in the same concentration and volume. The possibility of purchasing the wrong product (e.g., hives) that would have inappropriate instructions for a different indication (e.g., allergy).	Not reported

Appendix J: McNeil's Pharmacovigilance and Consumer Information Databases[***]

Medication Errors from McNeil's Pharmacovigilance Database

AERS Number	Medication Error Description
2008054103	Consumer stated that she accidentally gave her 19 month old child the Hives liquid instead of the Allergy liquid; wants to know is there any harm; doctor did recommend that she give the product to her child.
2009000760	Initial call: Accidentally gave Hives product to 15 month old child. Follow-up call: What is the difference between the hives product and the regular allergy product?

Medication Errors from Consumer Information Database

I wanted Zyrtec Allergy and accidentally purchased Zyrtec Hives for my daughter who has been on Zyrtec for 3 years now. Do I need to exchange my purchase or can I just go ahead and use this one?
gender is female, bought product, asked pharmacist, but still needed verification if the product has the same ingredients as the children's allergy
I accidentally bought this is this the same as regular zyrtec
What is the difference between the Zyrtec Hives Liquid and the Regular Zrytec Liquid for Children. I think I bought the wrong one.
The doctor recommended that we give our child Zyrtec for his allergies, and I bought this Zyrtec which says for hives from the drugstore. Is that any different from the Zyrtec for allergies?
I have been giving my 6 year old the Children's Zyrtec and when i bought this at the store it says hives on it but the pharmacits says its the same ingredient and I was calling to ask if that is true?
I have been using the Children's Zyrtec because thats all I need, but I bought this Zyrtec and it says on it its for hives, but the ingredients appear to be the same. Can I use this?
I purchased this children's hives instead of regular Zyrtec is it the same?
Children's Zyrtec Hives Syrup: My 8 year old son takes this product. He usually take the regular zyrtec but I bought this by mistake. The pharmacist said it was fine, it was the same exact product. Is it the same.
I was suppose had bought the zyrtec allergy instead I accidentally bought the zyrtec hives, my question is what is the difference between the two?
I bought the hives formula for children and it looks as if the ingredients are the same as the regular Zyrtec syrup are they the same?
has son who uses is 2 1/2 bought hives syrup by accident can i give this to him?

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

husband bought hives and not the allergy relief can my son still take this? did not have the box with her
Is there a difference between the Children's Zyrtec and the Children's Zyrtec HIVES formula? I bought the Hives formula on accident and returned it to Walgreen's. One of the clerks told me it had the exact same ingredients.
What is the difference between the allergy and this - I picked it up by mistake
I purchased the hive product instead of this product, will this still have work for my 11 year old daughter? Is it the same.
Consumer's grandson takes Zyrtec for allergies and this bottle says "Hives" and it looks different.
7 yr old normally takes Zyrtec for Children Allergy. My mom purchased Children's Zyrtec for Hives. Are they similar?
I purchased this product accidentally. I meant to purchase the Allergy syrup. Is there a difference between the two?
my 6 yr old uses Zyrtec, I just noticed I got the Hives Zyrtec for children, is it the same as the regular Zyrtec syrup?
is this the same as the other children's syrup because I bought this by accident but I see they have a common ingredient?
Consumer wanted to know if the product her daughter bought for grandson is there a difference between this product and the regular Zyrtec?
I have two products. One say for "hives" and the other is for "allergies" Why is that? Are they the same product
she wanted to double check with us, she was given zyrtec for hives at the store, what is the difference between the hives and zyrtec allergy syrup?
I purchased the Zyrtec hives by mistake but when I checked the ingredients they seem to be the same thing , is it?
I bought this by mistake-- look like the same as the childrens zyrtec
She has bought the wrong product and wants to know the difference between the regular syrup and the hives syrup
consumer bought and inquiring if there was a difference between this and hives relief
she bought children zyrtec with allergy on it, is there a difference between the hives and allergies syrup?
What is the difference between the two Zyrtec Syrup products? I purchased the Hives product to give to my 15 month old. Caller has not given the product to her child
Consumer picked up product for hives instead of regular one, can I use the product for hives and does it have the same ingredients?
I purchased the Zyrtec Hives product instead of the Zyrtec Allergy Syrup. How different are the two products?
she usually purchases children allergies and mistakenly purchased children's hives, what is the difference between the two? they both have the same ingredient.

my son has been on regular children's Zyrtec but I accidentally picked up the Zyrtec hive, what is the difference between the children's syrup and hives?
Consumer usually buys the product and bought the Hives formula, what is the difference between the two?
I have a bottle that reads 6yrs and older and has hives relief and there is the bottle that reads 2yrs and older and has allergy relief. The ingredients are the same, what is the difference?
I have two different products here and from what I'm reading they look like its the same thing Can you tell me what's different?
I have two of your Children's Liquids and these ingredients and mg's are the same, what is the difference?
I bought Children's Zytrec Hives relief from store, can I use this product for itchy eyes and runny nose for my child? I want to know the difference in the two products and the children's syrup. Pharmacy told me I could use this product.
my doctor gave me a sample of the CHILDREN'S ZYRTEC ALLERGY SYRUP. I went to the store and pick up the CHILDREN'S ZYRTEC HIVES SYRUP. they have the same ingredients so what is the difference in the products.
I bought this zyrtec hives syrup by mistake, is this the same as other
I bought this product by mistake is it a different type of product compared to the regular children's Zyrtec?
I've been giving this product to my child thinking it was the indoor/outdoor syrup. but then I reading the ingredients and it's the same as that product. Is there a difference between this and the other zyrtec syrup for kids grape flavor?
I just purchased this one and it says hives relief on the label, I normally get the one that has allergy written on the label, are these two products the same.
I purchased this product in error and I wanted to know if I'll still be able to use it for my son? I use the syrup for allergies and everything looks the same in the ingredients.
My children take this product for there allergies, This bottle I bought here says "Hives on it, are they the same thing?
I just purchased this product and it states "Hives" is this the same as the other Zyrtec liquid products?
I accidentally bought the hives one I see the indgredriedtents are the same.
My 6 year old takes this, one teaspoon a day, I sent my husband to the store and he got the children hives, is this the same as the allergy one.
She usually buys children's Zyrtec allergy and accidentally grabbed the children's hives, what is the difference between them?
She purchased a new bottle and the ingredients are different from the old one, she had Zyrtec hives.
the allergy and hives are both still the same but is so confusing everything is same still labeled differently

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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.

/s/

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12/08/2010

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