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

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Subject: Medication Error Postmarketing Safety Review

Drug Name(s): Lamisil (Terbinafine Hydrochloride Tablets) 250 mg
Application Type/Number: NDA 20-539

Lamisil (Terbinafine Hydrochloride Solution) 1%
NDA 20-749

Lamisil (Terbinafine) DermGel 1%
NDA 20-846

Lamisil (Terbinafine Hydrochloride Cream) 1%
NDA 20-980

Lamisil (Terbinafine Hydrochloride) Oral Granules
NDA 22-071

Applicant: Novartis Pharmaceutical Corporation

OSE RCM #: 2008-701

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The Institute of safe Medication Practices medication errors contains confidential and proprietary data, which cannot be shared outside the FDA.

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EXECUTIVE SUMMARY

The pediatric indication of use for the Lamisil oral granule formulation has had no impact on the existing medication errors reported to date with Lamisil. Both the proprietary and established names of Lamisil have been subject to name confusion. Medication errors with the established name, terbinafine have been limited and demonstrate no trend toward a particular problem with one name. We will continue to monitor these errors, however it is our opinion that these cases are isolated and require no regulatory action at this time.

The proprietary name continues to be confused primarily with Lamictal (lamotrigine) an antiepileptic drug. This confusion is limited to the oral tablet dosage form. The orthographic similarities of this name pair; similarities in dosage form (tablets), route of administration (oral), frequency (once daily), and numerical overlap of strength; we continue to receive reports of confusion despite the extensive educational campaign that has been developed to minimize this confusion.

Although we have noted a decrease in reporting, this decrease can be attributed to a number of factors such as, a decrease in reporting since the problem is well documented, continued education on the errors, inclusion of this pair on the Institute of Safe Medication Practices list of dangerous name pairs, and just the underreporting of medication errors in general. The introduction of the Rx Safety Advisor may also have had an impact on the reduction of errors as well. However, it is too early to draw any conclusions on the effectiveness of this intervention because it has not been fully implemented.

It is clear that no single intervention has been sufficient in managing these errors. Thus, the educational awareness of these errors and Rx Safety Advisor should be continued for the life of the product in the market. If we continue to receive errors of this nature then alternate measures need to be taken.

1 BACKGROUND

1.1 INTRODUCTION

This postmarketing safety review is written in response to a request from the Office of Pediatric Therapeutics and the Office of Pediatric and Maternal Health Staff to evaluate and summarize medication errors of name confusion involving Lamisil. This summary was requested in preparation for the November 17, 2008 Advisory Committee scheduled under the Best Pharmaceuticals for Children Act.

1.2 REGULATORY HISTORY

Lamisil was originally approved on December 30, 1992 under NDA 20-192. Since the original approval, seven NDA's have been approved containing the proprietary name Lamisil and the original NDA has been discontinued (see Appendix A). Pediatric Exclusivity was granted on December 4, 2006 for the Oral Granules (NDA 22-071).

Lamisil had no reported errors of name confusion until the approval of Lamisil 250 mg oral tablets in 1996. The strength of the newly formulated oral Lamisil tablets, 250 mg, provided numerical overlap with the already approved 25 mg tablets of Lamictal (see Appendix B). Lamictal, an antiepileptic drug used in the treatment of epilepsy and bipolar disorder, is manufactured by GlaxoSmithKline and is an oral tablet.

GlaxoSmithKline, the Applicant for Lamictal, has been active in raising awareness to the confusion between Lamisil and Lamictal. Since the proprietary name Lamictal was approved after the proprietary name Lamisil, GlaxoSmithKline would be responsible for any changes to the proprietary name, changes to the product, or subsequent actions necessary for the Applicant to maintain the proprietary name Lamictal. Following an increase in reported name confusion between Lamisil and Lamictal in 1997, a “Dear Pharmacist” letter was distributed by GlaxoSmithKline in June 1998.

Following the distribution of the “Dear Pharmacist” letter, errors continued to be reported. The concept of a name change for Lamictal was recommended in the review OSE# 00-0028 dated January 27, 2000. Because the errors continued to occur on March 28, 2000 the FDA requested a trademark change for Lamictal. In response to the Agency’s request, GlaxoSmithKline submitted a communication plan to decrease errors between Lamisil and Lamictal as an alternative to changing the trademark for Lamictal that included activities planned to promote awareness of name confusion to pharmacists, physicians and patients. Some of the planned actions include annual communication to healthcare professionals, computer flagging programs in chain pharmacies, error monitoring, shelf shouters, promotion of name confusion at pharmacy meetings, placing error messages in promotional materials, placing error messages in advertisements in medical journals, promotion of name confusion at physician conventions, placing an error message on the company website and providing brochures for epilepsy and bipolar disorders for patients. The communication plan was agreed upon by the Agency and was implemented in 2001.

On March 11, 2005 the possibility of a name change for Lamictal was reiterated via teleconference with GlaxoSmithKline because of an increase in reported errors to a spike of ten cases in 2004. On March 18, 2005 GlaxoSmithKline submitted justification for continuing the name Lamictal and provided an update on the communication plan agreed upon in 2001.

1.3 PRODUCT INFORMATION

Lamisil (terbinafine hydrochloride) is an allylamine antifungal. The currently marketed Lamisil products with their status, dosage form, strength, indications, and usual dosages are as follows:

Currently Marketed Lamisil Products				
Drug Name	Rx or OTC	Strength	Dosage Form	Usual Dose
Lamisil (Terbinafine Hydrochloride)	Rx	250 mg	Oral Tablet	Nail fungus: One tablet orally once daily
Lamisil (Terbinafine Hydrochloride)	Rx	125 mg/ packet 187.5 mg/ packet	Oral granules	Tinea capitis in patients 4 years of age and older: 125 mg, 187.5 mg, or 250 mg once a day for 6 weeks; dose is based upon body weight.
Lamisil (Terbinafine Hydrochloride)	Rx	1%	Topical Solution	Tinea (pityriasis) versicolor due to <i>Malassezia furfu</i> (formerly <i>Pityrosporum ovale</i>). Apply twice daily to affected area for 7 days.
Lamisil (Terbinafine Hydrochloride)	RX	1%	Topical Gel	Tinea (pityriasis) versicolor due to <i>Malassezia furfu</i> (formerly <i>Pityrosporum ovale</i>), tinea pedis (athlete's, foot), tinea corporis (ringworm) or tinea cruris (jock itch). Apply once daily to affected area for 7 days.
Lamisil AT Spray Pump (Terbinafine Hydrochloride) (<i>Athlete's Foot</i>)	OTC	1%	Topical Spray	Athlete's foot: Spray twice daily Ringworm/Jock itch: Spray once daily
Lamisil AT Spray Pump (Terbinafine Hydrochloride) (<i>Jock Itch</i>)	OTC	1%	Topical Spray	Jock itch: Spray once daily (morning or night)
Lamisil AT (Terbinafine Hydrochloride) (<i>Athlete's Foot</i>)	OTC	1%	Topical Cream	Athlete's foot: Apply twice daily Ringworm/Jock itch: Apply once daily
Lamisil AT (Terbinafine Hydrochloride) (<i>Jock Itch</i>)	OTC	1%	Topical Cream	Jock itch: Apply once daily (morning or night)
Lamisil AT (Terbinafine Hydrochloride) (<i>Athlete's Foot</i>) Targeted for Women	OTC	1%	Topical Cream	Athlete's foot: Apply twice daily
Lamisil AT Gel Advanced (Terbinafine Hydrochloride) (<i>Athlete's Foot</i>)	OTC	1%	Topical Gel	Athlete's foot: Apply once daily at bedtime Ringworm and jock itch: Apply once daily (morning or night)

2 METHODS AND MATERIALS

2.1 ADVERSE EVENT REPORTING SYSTEM (AERS) SELECTION OF CASES AND PERIODIC REPORTS SUBMITTED BY GLAXOSMITHKLINE

The Division of Medication Error Prevention searched the FDA Adverse Event Reporting System (AERS) database on June 25, 2008 to identify post-marketing cases involving name confusion associated with Lamisil. The MedDRA Higher Level Terms (HLT) "Maladministration", and "Medication Errors NEC"; Preferred Terms "Overdose", "Accidental overdose", "Accidental exposure", "Drug exposure via breast milk", "Drug exposure during pregnancy", "Transmission of drug via semen", "Unspecified agent exposure during pregnancy", "Accidental drug intake by child", "Drug exposure before pregnancy", and "Pharmaceutical complaint"; and tradename "Lamisil", active ingredient "Terbinafine", and verbatim "Lam%" and "Terbin%" were used as search criteria.

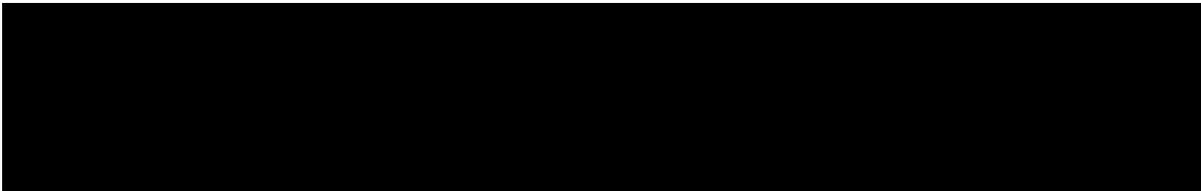
A separate AERS search was also conducted on June 25, 2008 to identify post-marketing cases involving name confusion associated with Lamictal. The MedDRA Higher Level Terms (HLT) “Maladministration”, and “Medication Errors NEC”; Preferred Terms “Overdose”, “Accidental overdose”, “Accidental exposure”, “Transmission of drug via semen”, “Accidental drug intake by child”, “Drug exposure before pregnancy”, and “Pharmaceutical complaint”; and tradename “Lamictal”, active ingredient “Lamotrigine”, and verbatim “Lam%” and was used as search criteria. Due to the number of reports the pregnancy related categories were removed from the search of Lamictal. Cases were manually reviewed for duplicates and for cases that did not involve medication errors. Those cases that did not involve medication errors were excluded from further analysis.

The periodic reports submitted by GlaxoSmithKline were cross referenced to the AERS cases, and all duplicates were removed.

2.2 MEDMARX DATABASE***



2.3 INSTITUTE FOR SAFE MEDICATION PRACTICES DATABASE***



3 RESULTS

3.1 ADVERSE EVENT REPORTING SYSTEM (AERS) AND REPORTS SUBMITTED BY GLAXOSMITHKLINE

A total of 194 cases associated with Lamisil and 465 cases associated with Lamictal were retrieved on June 25, 2008 from the AERS database search. Additionally, the periodic reports submitted by GlaxoSmithKline identified 64 cases. After removing duplicate cases, those that did not contain a medication error, and those cases that did not involve name confusion associated with Lamisil a total of ninety two (n=92) cases were further analyzed (see Appendix C for summaries). Analysis of these 92 cases follows:

3.1.1 Lamisil Name Confusion with Names Other than Lamictal (n=13)

Thirteen cases reported name confusion between Lamisil and drug names other than Lamictal. Two cases were foreign and the remaining were domestic. None of the cases reported the type of order (written or verbal). The majority of cases occurred within 3 years of Lamisil’s approval in 1996. These errors may have been precipitated by practitioner’s unfamiliarity with the approval of Lamisil tablets. However, none of these cases offer a discernable trend of continued confusion with Lamisil (See Table 1 Page 7 for summary).

Table 1:

Lamisil Name Confusion with Names Other than Lamictal (n=11)					
Drug Name	Number of Cases and Years in which Errors Occurred	Location	Medication Ordered Medication Received	Outcome	Causality
Baccidal (norfloxacin)	n=1 2003	Foreign	Ordered: Baccidal (norfloxacin) Received: Lamisil	Hospitalization	None Reported
Ketoconazole*	n=1 1999	Domestic	Ordered: ketoconazole Received: Lamisil	Hospitalization	None Reported
Lariam	n=3 Unknown 1997 1999	Domestic	Ordered: Lamisil Received: Lariam	Unknown (1) Intervention Required (1) Permanent Harm (1)	None Reported
Lanoxin	n=1 2001	Domestic	Ordered: Lamisil Received: Lanoxin	Patient did not receive a dose	Placement on Shelf
Lomotil	n=4** 1996 (2); 1999; 2002	Domestic	Ordered: Lamisil Received: Lomotil	No Patient Involvement (3) Patient did not receive a dose (1)	Similar Names (3) None Reported (1)
Terfenadine [◇]	n=1 1996	Domestic	Ordered: NA Received: NA	No Patient Involvement	Similar names
Tramadol spray	n=1 2007	Foreign	Ordered: Tramadol spray Received: Lamisil	None Reported	None Reported
Zyrtec	n=1 2007	Domestic	Ordered: Zyrtec Received: Lamisil	None Reported	Work Environment (busy pharmacy)

* This case involved a 16 year old female which resulted in hospitalization.

** Four (n=4) cases of name confusion include three (n=3) complaints of possible name confusion. Only one report involved a patient.

[◇] Complaint of possible name confusion with established name of Lamisil (Terfenadine vs. Terbinafine). Terfenadine is currently not marketed in the United States

3.1.2 Lamisil and Lamictal (n=79)

Seventy-nine cases reported confusion between Lamisil and Lamictal beginning in 1996 through 2008. These errors resulted in a range of outcomes from no adverse event to death. Ten of these cases were foreign and the remaining were domestic reports. The name confusion errors occur regardless of whether or not Lamisil or Lamictal was ordered. All cases involved the oral tablet formulation. The majority of cases (75 cases) occurred in patients greater 17 years of age.

There were 4 errors that occurred in patients under the age of 16 years of age and young. These pediatric cases are described in table 2 below for ease of review since the Division was most interested in pediatric errors.

Table 2:

Lamisil Name Confusion with Lamictal in Patients 16 Years of age and Younger (n=4)						
Age Range	Actual age	Medication Ordered Medication Received	Location	Outcome	Causality	Years in which Errors reported
0 years to 1 year	1 year of age	Ordered: Lamictal Received: Lamisil	Netherlands	Intervention required Inflamed eye and an abnormal ECG	None Reported	2001
2 years to 5 years	NA	NA	NA	NA	NA	NA
6 years to 11 years	8 years of age	Ordered: Lamictal Received: Lamisil	Michigan	None reported	None Reported	1998
	9 years of age	Ordered: Lamisil Received: Lamictal	South Carolina	Hospitalization	Similar Names	2001
12 years to 16 years	16 years of age	Ordered: Lamictal Received: Lamisil	New York	Increase seizures	None Reported	1997

The remaining 75 cases involving Lamisil and Lamictal confusion occurred in patients 17 years of age and older. Table 3 describes the outcome of these cases along with reported causality. When causality was reported the confusion was attributed to the similar names and computer selection error upon data entry.

Table 3:**Name Confusion between Lamisil and Lamictal Identified in AERS for Patient 17 years of Age and Older or Unknown**

Outcome	Location	Year	Medication Ordered	Medication Received	Causality
Death (n=5)	Foreign	2004	Lamisil	Lamictal	Computer Selection Error
	Foreign	2004	Lamisil	Lamictal	Computer Selection Error
	Foreign	2005	Lamisil	Lamictal	None Reported
	Domestic	2005	Lamictal	Lamisil	None Reported
	Domestic	2007	Lamictal	Lamisil	None Reported
Initial or Prolonged Hospitalization (n=6)	Domestic	1998	Lamisil	Lamictal	None Reported
	Domestic	2000	Lamictal	Lamisil	None Reported
	Foreign	2004	Lamisil	Lamictal	None Reported
	Domestic	2006	Lamisil	Lamictal	None Reported
	Domestic	2006	Lamisil	Lamictal	None Reported
	Foreign	2007	Lamisil	Lamictal	None Reported
Increase in Seizures (n=3)	Domestic	1997	Lamictal	Lamisil	None Reported
	Domestic	1998	Lamictal	Lamisil	Similar Names
	Domestic	2000	Lamictal	Lamisil	None Reported

Table 3 Continued:

Name Confusion between Lamisil and Lamictal Identified in AERS for Patient 17 years of Age and Older or Unknown

Outcome	Location	Year	Medication Ordered	Medication Received	Causality
Rash (n=7)	Domestic	1998	Lamisil	Lamictal	None Reported
	Domestic	1999	Lamisil	Lamictal	None Reported
	Domestic	1999	Lamisil	Lamictal	None Reported
	Domestic	2003	Lamisil	Lamictal	None Reported
	Domestic	2003	Lamisil	Lamictal	None Reported
	Domestic	2004	Lamisil	Lamictal	None Reported
	Foreign	2004	Lamisil	Lamictal	None Reported
Intervention Required (n=6)	Foreign	1996	Lamisil	Lamictal	None Reported
	Domestic	1997	Lamisil	Lamictal	None Reported
	Domestic	2000	Lamisil	Lamictal	Similar Names
	Domestic	2003	Lamisil	Lamictal	None Reported
	Domestic	2003	Lamisil	Lamictal	Stress (distracted by putting away order)
	Foreign	2005	Lamisil	Lamictal	None Reported
Delay in Treatment (n=3)	Domestic	2006	Lamictal	Lamisil	Similar Names
	Foreign	2007	Lamisil	Lamictal	None Reported
	Domestic	2008	Lamisil	Lamictal	Computer Selection Error

Table 3 Continued:

Name Confusion between Lamisil and Lamictal Identified in AERS for Patient 17 years of Age and Older or Unknown

Outcome	Location	Year	Medication Ordered	Medication Received	Causality
Suicidal (n=1)	Domestic	2002	Lamictal	Lamisil	None Reported
Minor Adverse Events (n=12)	Foreign	1996	Lamisil	Lamictal	None Reported
	Foreign	1996	Lamisil	Lamictal	None Reported
	Domestic	1999	Lamictal	Lamisil	None Reported
	Domestic	1999	Unknown	Unknown	None Reported
	Domestic	2000	Lamisil	Lamictal	None Reported
	Domestic	2003	Lamictal	Lamisil	None Reported
	Foreign	2004	Lamictal	Lamisil	Similar Tablets
	Domestic	2004	Lamisil	Lamictal	None Reported
	Domestic	2004	Lamictal	Lamisil	None Reported
	Domestic	2004	Lamictal	Lamisil	None Reported
	Foreign	2005	Lamictal	Lamisil	None Reported
	Domestic	2006	Lamisil	Lamictal	None Reported

Table 3 Continued:

Name Confusion between Lamisil and Lamictal Identified in AERS for Patient 17 years of Age and Older or Unknown

Outcome	Location	Year	Medication Ordered	Medication Received	Causality
Patient Did Not Receive Any Doses (n=16)	Domestic	1996	Unknown	Unknown	Similar Names
	Domestic	1996	Unknown	Unknown	Similar Names
	Domestic	1996	Lamisil	Lamictal	None Reported
	Domestic	1997	Unknown	Unknown	Similar Names
	Domestic	1998	Lamictal	Lamisil	None Reported
	Domestic	1998	Unknown	Unknown	Close Proximity to each other on Shelf
	Domestic	1999	Unknown	Unknown	Similar Names
	Domestic	1999	Lamictal	Lamisil	None Reported
	Domestic	1999	Lamisil	Lamictal	Computer Selection Error
	Domestic	1999	Lamisil	Lamictal	Computer Selection Error
	Domestic	2000	Lamictal	Lamisil	None Reported
	Foreign	2001	Unknown	Unknown	Similar Names
	Domestic	2003	Lamictal	Lamisil	None Reported
	Domestic	2004	Lamisil	Lamictal	Misspelled Names and Similar Names
	Domestic	2006	Lamisil	Lamictal	Illegible prescription
	Domestic	2006	Lamisil	Lamictal	None Reported

Table 3 Continued:

Name Confusion between Lamisil and Lamictal Identified in AERS for Patient 17 years of Age and Older or Unknown

Outcome	Location	Year	Medication Ordered	Medication Received	Causality
No Adverse Event Reported (n=5)	Domestic	1997	Lamictal	Lamisil	None Reported
	Domestic	2005	Lamictal	Lamisil	None Reported
	Domestic	2006	Lamictal	Lamisil	None Reported
	Domestic	2006	Lamisil	Lamictal	None Reported
	Domestic	2007	Lamictal	Lamisil	None Reported
Unknown (n=10)	Domestic	1996	Lamisil	Lamictal	None Reported
	Domestic	1997	Lamisil	Lamictal	Stress (Workload)
	Domestic	1997	Lamisil	Lamictal	None Reported
	Domestic	1997	Unknown	Unknown	Similar Names
	Domestic	1999	Lamisil	Lamictal	None Reported
	Domestic	2000	Lamisil	Lamictal	Similar Names
	Domestic	2001	Lamisil	Lamictal	None Reported
	Domestic	2001	Lamisil	Lamictal	None Reported
	Domestic	2004	Lamisil	Lamictal	None Reported
	Domestic	2005	Lamictal	Lamisil	None Reported
	Unknown	2005	Lamisil	Lamictal	None Reported

3.2 MEDMARX DATABASE*** [REDACTED]

[REDACTED]

3.2.1 [REDACTED]

[REDACTED]

Table 5:

MedMarx*** [REDACTED]

[REDACTED]

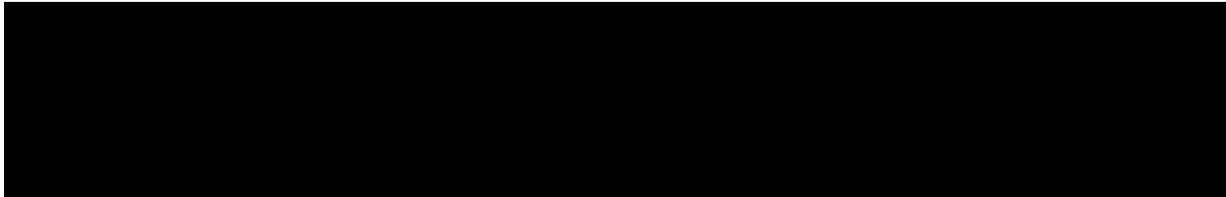
3.2.2 [REDACTED]

[REDACTED]

Table 6:



3.3 INSTITUTE FOR SAFE MEDICATION PRACTICES DATABASES***



4 DISCUSSION

We evaluated all cases of name confusion reported with the proprietary name Lamisil. In addition to summarizing all cases of name confusion, we were asked to assess whether or not the approval of the pediatric formulation had any impact on the medication errors reported with Lamisil. We have no evidence to support that the approval of the pediatric dosage form, Lamisil Oral Granules, has increased the risk of errors seen with Lamisil name confusion.

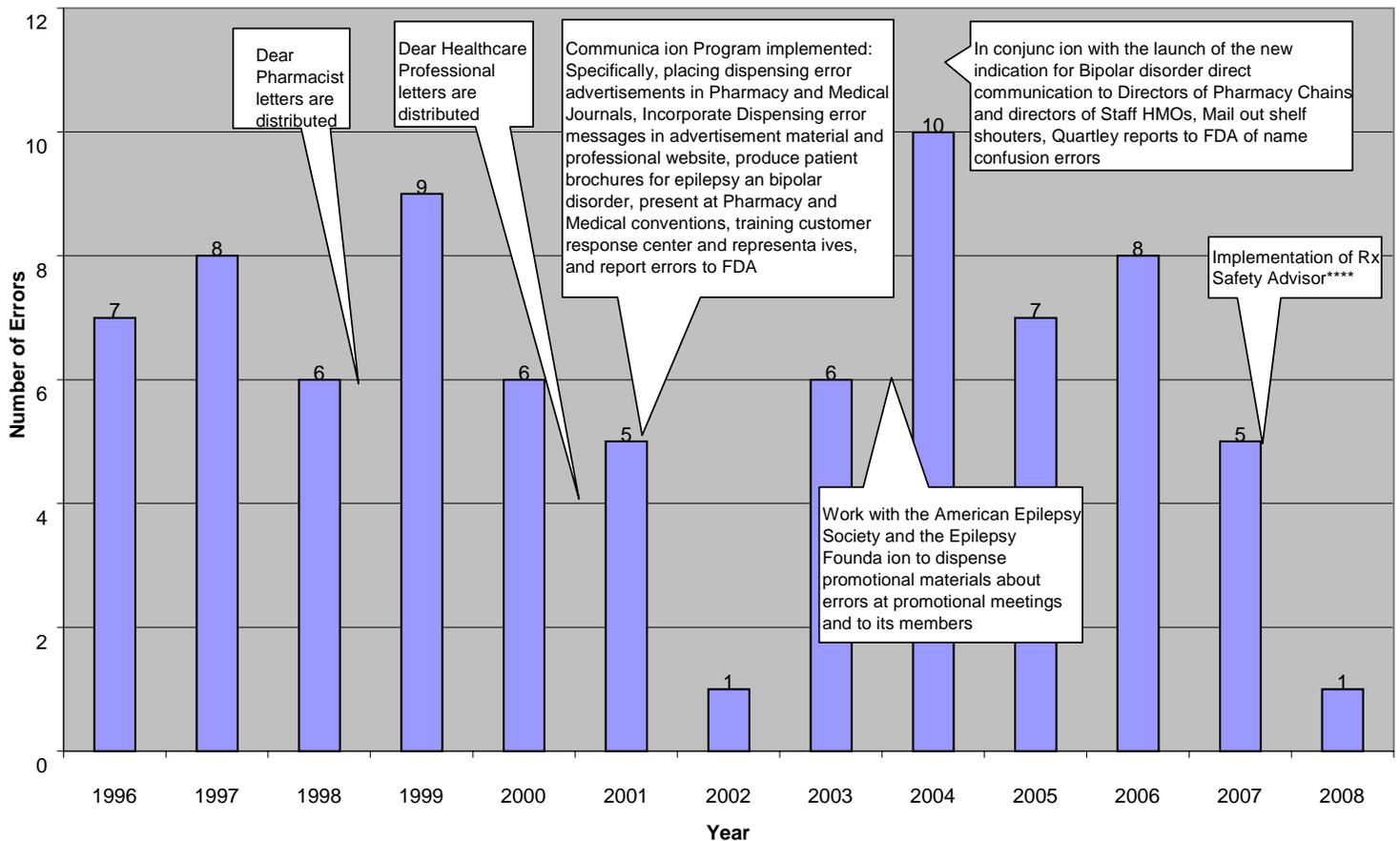
Our evaluation of the combined data on the proprietary name confusion with Lamisil, we noted both the established and proprietary names have been a source of error. However, the major problem is with the proprietary name. The data obtained from outside reporting programs supported the findings of our evaluation of cases in AERS and those submitted by GlaxoSmithKline. There have been fourteen (14) different names confused with Lamisil since it was approved 12 years ago. We are unable to determine if name confusion or another factor, such as close proximity on a shelf produced the errors for 13 of the 14 names identified. However, Lamictal confusion has been reported multiple times in multiple databases and continues to occur despite efforts to reduce medication errors between this name pair.

It is interesting to note that name confusion between Lamisil and Lamictal was not reported until after the approval of Lamisil oral tablets on March 10, 1996. The confusion appears to be limited to the tablet formulation. Lamisil and Lamictal were co-marketed for several years, without confusion, and always had some orthographic and phonetic similarity to one another. However, the approval of the tablets provided new and similar overlapping product characteristics (see Appendix B) that have contributed to the confusion between Lamisil and Lamictal. The tablet formulation provided for overlap in dosage form, frequency of dosing (once daily), and a numerical similarity in dosage strength (25 mg vs. 250 mg).

The cases of proprietary name confusion do not appear to be linked to any particular practice setting of care as errors were reported from all practice settings.

Although, efforts have been taken to raise awareness of the potential name confusion between Lamisil and Lamictal, such as Dear Healthcare Professional letters, “shelf shouters”, and implementation of computer software that monitors for name confusion of Lamisil and Lamictal, errors continue to occur. The graph below illustrates the time frame in which these interventions were employed as compared to the number of reports received in AERS and the periodic reports. The data from outside sources show a comparable number of reports per year.

Lamisil and Lamictal Confusion (n=79)



**** Safety RX Advisor is a software program that alerts Pharmacist or potential Look-alike or sound-alike names. A warning message is displayed prior to the claim being made and after the claim is accepted. An override code must be entered to bypass the message. Unlike many pharmacy warning systems this message cannot be paged through.

5 CONCLUSION AND RECOMMENDATIONS

The pediatric indication of use for the oral granules has not been shown to exacerbate existing medication errors reported due to name confusion with Lamisil. The largest number of medication errors reported with Lamisil are the result of proprietary name confusion between Lamisil and Lamictal for the tablet formulation. The interventions to date have not been fully effective in minimizing these errors. However, the RX Safety Advisor component of the sponsor's interventions has just been implemented in 2007 and thus we will need to monitor these errors over the course of the next year to determine its impact. If the errors with Lamictal and Lamisil continue to occur over the next years we will need to consider other alternative methods to minimize the occurrence of these errors. We recommend the following:

1. Continue the communication program developed by GlaxoSmithKline and the FDA for the life of the product.
2. Continue to monitor the effectiveness of the RX Safety Advisor. If the RX Safety Advisor does not have a positive impact on the reduction of the name confusion, consider additional options to minimize this risk.
3. Work with the Institute for Safe Medication Practices to have the name pair Lamisil and Lamictal placed on the Joint Commission list of Look-alike and Sound-alike names.
4. Monitor name confusion with the established name.

6 REFERENCES

6.1 REVIEWS

OSE Review #02-0028 Post-Marketing Review for Lamictal Chewable Dispersible Tablets (Lamotrigine) and Lamisil (Terbinafine HCL Tablets), Lee, L; January 27, 2005.

6.2 ADVERSE EVENTS REPORTING SYSTEM (AERS)

AERS is a database application in CDER FDA that contains adverse event reports for approved drugs and therapeutic biologics. These reports are submitted to the FDA mostly from the manufactures that have approved products in the U.S. The main utility of a spontaneous reporting system that captures reports from health care professionals and consumers, such as AERS, is to identify potential postmarketing safety issues. There are inherent limitations to the voluntary or spontaneous reporting system, such as underreporting and duplicate reporting; for any given report, there is no certainty that the reported suspect product(s) caused the reported adverse event(s); and raw counts from AERS cannot be used to calculate incidence rates or estimates of drug risk for a particular product or used for comparing risk between products.

6.3 MEDMARX (

[REDACTED]

[REDACTED]

6.4 INSTITUTE FOR SAFE MEDICATION PRACTICES DATABASES***

[REDACTED]

APPENDICES

APPENDIX A: LAMISIL PRODUCTS WITH NDA'S AND APPROVAL DATES

Drug name & NDA#	Strength	Dosage form	Marketing Status	Approval Date
Lamisil NDA #20-539	250 mg	Oral Tablet	Prescription	March 10, 1996
Lamisil NDA #22-071	125 mg/packet 187.5 mg/packet	Oral Granule	Prescription	September 28,2007
Lamisil NDA #20-749	1%	Topical Solution	Prescription	October 17,1997
Lamisil NDA #20-846	1%	Topical Gel	Prescription	April 29, 1998
Lamisil NDA #20-980	1%	Topical Cream	Over-the-counter	March 09, 1999
Lamisil AT NDA #21-124	1%	Topical Solution Topical Spray	Over-the-counter	March 17, 2000
Lamisil AT NDA #21-958	1%	Topical Gel	Over-the-counter	July 24, 2006
Lamisil NDA #20-192	1%	Topical Cream	Discontinued	December 12, 1992

APPENDIX B: COMPARISON OF LAMISIL AND LAMICTAL PRODUCT CHARACTERISTICS

Drug Name	Rx or OTC	Strength	Frequency	Dosage Form	Route	Indication of Use and Frequency of Administration
Lamictal (Lamotrigine Hydrochloride)	Rx	25 mg, 100 mg, 150 mg, and 200 mg	Once to twice daily	Tablets	Oral	Epilepsy and Bipolar disorder
Lamisil (Terbinafine Hydrochloride)	Rx	250 mg	Once Daily	Tablet	Oral	Nail fungus

APPENDIX C: AERS CASES AND CASES SUBMITTED BY GLAXOSMITHKLINE

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
USP ID: 51795	UNK	9/18/1998	US	Unknown	Unknown	close to each other on shelf	Patient did not receive any doses	Potential- Lamictal and Lamisil close to each other on shelf
ISR Number: 1892470	16	15-Feb-97	US	Lamictal	Lamisil	None reported	Seizures	This 16 year old male patient with a history of seizure and mental retardation was accidentally dispensed Lamisil tablets instead of Lamictal. The patient took 5 Lamisil tablets a day for four days (1250 mg/day). The patient experiences daily seizures but on the third and fourth day of Lamisil overdose, he experienced "a few more than normal". The outcome is unknown. Concomitant medications include Tegeretol. Additional information has been requested. NEW DATA (21-MAR-97): The reporter stated that after the patient was put back on Lamictal the seizures were back under control and the sedation cleared up. The reporter additionally noted that no other problems had been seen.
ISR Number: 1897935	33	6-Jan-97	US	Lamictal	Lamisil	None reported	No Adverse Event reported	Pt. was taking Lamotrigine (Lamictal) 100 mg q AM and 150 mg q AM for epilepsy. Pharmacist erroneously substituted Lamisal 205mg. Refill pill bottle was correctly labeled, but contained Lamisal. On admission to hospital (for other reason) I noted the error. There was no adverse effects, possibly because of co medications.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3024447	40	5-Jan-98	US	Lamictal	Lamisil	None reported	Patient did not receive any doses	PATIENT WENT IN TO [REDACTED] TO REFILL HER LAMICTAL (LAMOTRIGINE) 150 MG. SHE HAS TEMPORAL LOBE EPILEPSY AND COMPLEX PARTIAL SEIZURES. THE BOTTLE WAS CORRECTLY LABELLED, BUT IT CONTAINED LAMISIL (TERBINAPINE) 250 MG. PATIENT NOTED ERROR, BUT ALMOST TOOK PILLS ANYWAY. SHE DECIDED TO CALL THE PHARMACY WHICH CONFIRMED INCORRECT DISPENSARY. PATIENT NEVER TOOK THE LAMISIL, AND BEGAN TAKING A REPLACEMENT RX FOR LAMICTAL.
ISR Number: 3080526	8	25-Feb-98	US	Lamictal	Lamisil	None reported	None reported	ORDERED LAMICTAL, GIVEN LAMISIL. STATUS EPILEPTICUS
ISR Number: 3080530	72	12-Dec-97	US	Lamisil	Lamictal	None reported	Intervention	DECREASE BLOOD PRESSURE. DECREASED O2 SATS. ORDERED LAMISIL GIVEN LAMICTAL.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3214523	50	24-Dec-98	US	Lamisil	Lamictal	None reported	Hospitalization	A PHYSICIAN REPORTED THAT A 50 YEAR OLD FEMALE PATIENT RECEIVED ORAL LAMOTRIGINE (LAMICTAL) FOR EIGHT DAYS AND DEVELOPED A GENERALIZED RASH AND ELEVATED HEPATIC ENZYMES (ALT 586, AST 351). UPON FOLLOW UP, THE PHYSICIAN REPORTED THAT THE PATIENT WAS PRESCRIBED ORAL TERBINAFFINE (LAMISIL) BUT THE PRESCRIPTION WAS FILLED WITH ORAL LAMOTRIGINE AT THE TERBINAFFINE DOSAGE. THE PHYSICIAN REPORTED THAT SHE ALSO DEVELOPED FATIGUE AND WAS ADMITTED TO THE HOSPITAL WHERE THE PHYSICIAN NOTED SHE HAD CONCURRENTLY DEVELOPED HEPATITIS C THAT HE FELT WAS DRUG INDUCED. SHE WAS TREATED WITH INTRAVENOUS FLUIDS AND PREDNISONE, LAMOTRIGINE WAS DISCONTINUED AND THE EVENTS RESOLVED. HER LIVER FUNCTIONS RETURNED TO NORMAL. THE PHYSICIAN WAS ALMOST CERTAIN THE EVENTS WERE RELATED TO LAMOTRIGINE. ADDITIONAL FOLLOW UP REPORTED BY ANOTHER PHYSICIAN INDICATED THE PATIENT WAS HOSPITALIZED AND REQUIRED CLINICAL INTERVENTION FOR THE EVENTS.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3230273	No patient involved	3/19/1999	US	Unknown	Unknown	Names sound similar and are almost identical in spelling	Patient did not receive any doses	THE NAMES OF THESE MEDICATION SOUND ALMOST ALIKE AND ARE ALMOST IDENTICAL IN SPELLING. WHENEVER A PHARMACIST IS IN DOUBT, ASK FOR AN INDICATION OR HAVE THE PERSON CALLING THE PRESCRIPTION IN SPELL OUT THE MEDICATION. ***DRUG MALADMINISTRATION***
ISR Number: 3260293	UNK	4-Feb-99	US	Lamisil	Lamictal	Picked name from drop down list on computer	Patient did not receive any doses	LAMICTAL WAS DISPENSED FOR THE PRESCRIBED LAMISIL. MEDICATION MALADMINISTRATION
ISR Number: 3335751	39	11-Jun-99	US	Lamisil	Lamictal	None reported	Rash	LAMICTAL WAS DISPENSED INSTEAD OF LAMISIL. THE REPORTER (PATIENT) TOOK THE WRONG DRUG FOR ONE MONTH. ALTHOUGH PRINTED INFORMATION WAS GIVEN TO THE REPORTER, SHE ONLY GLANCED AT IT , PRESUMING THAT SHE HAD RECEIVED THE CORRECT MEDICATION. *****DRUG MALADMINISTRATION*****
ISR Number: 3411739	UNK	21-Oct-99	US	Lamictal	Lamisil	None reported	Patient did not receive any doses	THE PRESCRIPTION READ LAMICTAL 25 MG TWO TABLETS TWICE A DAY ; LAMISIL 250 MG WAS DISPENSED. "DRUG MALADMINISTRATION"
ISR Number: 3450733	UNK	19-Feb-99	US	Lamictal	Lamisil	None reported	Minor side effects	A PRESCRIPTION WAS CALLED IN FOR LAMICTAL 25MG AND WAS PROPERLY LABELED BUT WAS FILLED WITH LAMISIL 250MG. DRUG MALADMINISTRATION

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3526182	UNK	4/5/2000	US	Lamisil	Lamictal	Similarity of the names	Unknown	<p>DRUG MALADMINISTRATION A report was transcribed from the automated MedWatch product problem reporting line: The similarity of the brand names of these two products have caused confusion over the phone. A doctor's nurse called in a prescription which was supposed to be for Lamisil, and it was taken by the pharmacist, myself, as Lamictal. Med watch staff member, David Konigstein, RPH, contacted the reporter for additional information. The product was prescribed by a dermatologist. The reporter heard Lamictal and questioned the nurse, "Are you sure it's Lamictal?" and she said yes. This occurred 3 months ago. The prescription was dispensed as Lamictal. The reporter had no idea anything was amiss until recently, when the patient's mother brought it to the attention of the doctor. The nurse now states she did not call it in as Lamictal. The young man is undergoing some testing. The reporter has no additional details about any adverse advents, if any, that occurred. The reporter remarked that he questioned things, but dermatologists are increasingly using things off-label. For example, he just learned that they are prescribing Neoral Capsules to be opened up and the contents used topically on a wound.</p> <p>DRUG MALADMINISTRATION</p>
ISR Number: 3597440	31	1-Dec-98	US	Lamictal	Lamisil	Similarity of the names	Seizures	<p>Pharmacy erroneously substituted Lamisil (Terbinafine) for Lamictal (lamotrigine). She has chronic, severe (L) temporal lobe epilepsy. Her seizures became much more frequent. drug maladministration.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3613395	UNK	11/8/2000	US	Lamictal	Lamisil	None reported	Seizures	Seizures[Convulsions NOS] Inadvertent exposure to drug[Accidental exposure] Case Description: Serious spontaneous report (medically significant hazard), assessed as unlisted according to the Basic Prescribing Information. The information provided in this individual case does not warrant a change to the Basic Prescribing Information text. The topic will be monitored closely and will be re-evaluated on an ongoing basis based on cumulative experience. All spontaneous reports are considered suspected for reporting purposes.
ISR Number: 3618735	UNK	11/21/2000	US	Lamictal	Lamisil	None reported	Patient did not receive any doses	The reporter was informed that a prescription he wrote for Lamictal 50 mg was filled with Lamisil. The pharmacy caught the error before the patient left. The patient never took the wrong product. The reporter does not have any additional information.
ISR Number: 3683483	9	25-Jan-01	US	Lamisil	Lamictal	Similarity of the names	Hospitalization	Lamisil 250mg daily was ordered; Lamictal 200mg was dispensed. The patient took the wrong medication for nine days. DRUG MALADMINISTRATION
ISR Number: 3738247	36	31-May-01	Foreign	Lamictal	Lamisil	Similarity of the names	Patient did not receive any doses	MED ERROR A pharmacy in Canada refilled (new Rx for that pharmacy) the patient's antiepileptic drug. Lamictal (lamotrigine) 200 mg po bid was prescribed. They dispensed terbinafine generic (brand nameL Laamisil) 250 mg. They erroneously mailed the drug bottles to us and I noted the error. The patient never received the medication bottles. "MED ERROR"

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3762565	UNK	4/1/2001	US	Lamisil	Lamictal	None reported	Unknown	DRUG MALADMINISTRATION On a new prescription, Lamictal 25mg was dispensed instead of Lamisil. The container was labeled "Lamisil" and the patient information leaflet given to the patient was for "Lamisil". The reporter took Lamictal for one month. When the prescription was refilled at a different pharmacy, the reporter noticed that the tablets were different. This prescription was dispensed in the manufacturer's container. Lamisil was prescribed to treat a toenail fungus.
ISR Number: 3764314	58	23-Jul-01	US	Lamisil	Lamictal	None reported	Unknown	Order for Lamisil 250mg mis-read as Lamictal 250mg. Filled with Lamictal 250mg. Drug Maladministration

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 3949752	1	12/1/2001	NL	Lamictal	Lamisil	None reported	Intervention required	<p>Dry eyes[Dry eye NOS] Inflamed eyes[Eye inflammation NOS] Patient received by mistake Lamisil instead of Lamictal[Medication error] Case Description: This one year old child received by mistake Lamisil (terbinafine) for 2 months, instead of Lamictal (lamotrigine). The dosage was titrated up to 600 mg/day. The pharmacist reported that the child experienced dry and inflamed eyes. The reaction was treated with an eye cream. The outcome was unknown. Follow-up information received on 08 Mar 2002: The patient's date of birth was provided. At the moment the patient is fine and has no side effects. No abnormality in liver enzymes was found. In Dec 2001, the patient suffered from a long insult. After investigation it seemed that she had an abnormality in the EEG. The physician prescribed by mistake Lamisil instead of Lamictal. The pharmacist made a suspension of 25 mg/mL of Lamisil. Follow-up information received on 18 Apr 2002: As of this report, the patient is doing well. The pediatrician decided to give no Lamictal anymore since the patient has no insults (one single episode in Dec 2001). The inflamed eyes seemed to be a "real inflammation" as consequence of Lamisil intake. Follow-up information received on 09 Jul 2002: The patient is going well. She is under supervision from a pediatrician.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4001441	UNK	10/24/2002	US	Lamictal	Lamisil	None reported	Suicidal	A physician reported the occurrence of a dispensing error where a patient received terbinafine (Lamisil) tablets (120mg three times daily) instead of her lamotrigine (Lamictal-formulation unknown) tablets and became acutely suicidal. She received the terbinafine tablets for 10 days before the dispensing error was discovered. The patient had never been acutely suicidal before. No further information provided. No previous history of suicidal tendencies. Pt received terbinafine instead of lamotrigine
ISR Number: 4095556	50	2/7/2003	US	Lamisil	Lamictal	Distracted by putting away warehouse order, similar names, and shelf location.	Intervention required	Rash[Rash NOS] Redness[Erythema] Dispensing error[Medication error] Case Description: This report received from the USP Medication Errors Reporting Program: A pharmacist reports of a dispensing error resulting in a rash and redness after a patient was inadvertently dispensed Lamictal (lamotrigine) instead of the prescribed Lamisil. The events occurred after an indeterminate amount of time, with the patient consulting with her primary care physician. Final outcome was not provided.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4112797	40	5/2/2003	US	Lamictal	Lamisil	None reported	Minor Adverse events	Irritability [Irritability] Insomnia [Insomnia] Agitation [Agitation] Condition aggravated [Condition aggravated] Dispensing error [Medication error] Case Description: This report from GlaxoSmithKline, Ref#A0401559A: A physician reports a medication error in which a patient on ongoing therapy with Lamictal (lamotrigine) was inadvertently dispensed Lamisil tablets. After two weeks of the inadvertent Lamisil therapy the patient's underlying condition of bipolar disorder, for which the Lamictal was prescribed, became aggravated, resulting in irritability, agitation and insomnia. The error was discovered by the physician, who discontinued the Lamisil. Final outcome of the reported events was not provided. Novartis Comment: Serious spontaneous report [medically significant], assessed as unlisted according to the Basic Prescribing Information. The information provided in this individual case does not warrant a change to the Basic Prescribing Information text. The topic will be monitored closely and will be re-evaluated on an ongoing basis based on cumulative experience. All spontaneous reports are considered suspected for reporting purposes. The available information was considered inadequate to fully assess the case.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4152868	50	9-Jun-03	US	Lamisil	Lamictal	None reported	Intervention required	<p>The pt, the reporter's spouse and also an RN, received Lamictal from the pharmacy rather than the prescribed Lamisil indicated for toenail onychomycosis. She used the Lamictal as was directed for the Lamisil, 1 tab daily. She experienced multiple adverse events. She started the drug on 6/4. On 6/9, she developed a severe one-sided headache. She went to her doctor the very next day. There was thought she was having a cerebral hemorrhage. Additionally, she was hypertensive, with a BP of 170/98. A brain scan, blood tests, and an EKG were done. Everything was okay. She was also prescribed Toprol XL for her BP, but it wasn't filled. On follow-up check one week later, her BP was still moderately elevated. Other symptoms she experienced were fatigue, somnolence, extreme flushing/warmth, swollen hands (her rings were tight), and a peeling rash on one finger which is new x 4 days. She's had a continuous, persistent low grade headache throughout the month. There was concern about stopping it suddenly, considering Lamictal is never started at such a high dose. A neurologist was consulted and the reply was it should be okay because she doesn't have a hx of seizures and wouldn't be prone to any seizure activity. Her last dose was taken 7.1. The error was detected when her employer, a family practice physician, gave her some Lamisil samples. She noticed the tablets looked completely different - color, shape, and company. When she checked her prescription vial, the label reads "Lamisil". The tablets read "Lamictal". The label had the mg strength and qty circled, and it was supposedly checked. The pharmacist took responsibility for the error. She'll start the correct drug, Lamisil, in perhaps a week's time to allow for clearance of the Lamictal</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4169434	20	10/24/1997	US	Lamisil	Lamictal	None reported	Unknown	MEDICATION ERROR Pt. was given Rx by podiatrist to treat toe nail fungus for Lamisil 250 mg. Lamictal 25 mg was dispensed. Pt received 3-day supply which he took before transferring Rx.
ISR Number: 4170167	33	8-Apr-97	US	Lamictal	Lamisil	similar names	Seizures	On a refill, a patient was dispensed Lamisil 250 mg instead of lamicaltal 150 mg. The patient put the few remaining tablets from her old refill in with the new tablets and took 25 doses. The tablets of the two products are not quite the same and yet not totally different. medication error
ISR Number: 4189586	83	7-Nov-96	US	Lamisil	Lamictal	None reported	Unknown	RPH received an order for Lamsil 250 mg OD x 90 days it was checked by second pharmacist, it was entered as Lamictal 25 mg QD and sent out to a LTC facility, medication was given to the patient by various LPN's and RN's. patient received #37 doses. medication error
ISR Number: 4209953	UNK	20-Oct-96	US	Lamisil	Lamictal	None reported	Patient did not receive any doses	The pharmacist was working as a relief pharmacist when the incident occurred The pharmacist did not recall the patient nor the misfill. medication error
ISR Number: 4243147	17	11-Aug-03	US	Lamictal	Lamisil	None reported	Patient did not receive any doses	Lamisil was dispensed instead of Lamictal. Pt realized appearance of med was different she returned to pharmacy & correct med was dispensed No dose was taken. Medication error

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4261482	No patient involved	7/25/1996	US	Unknown	Unknown	Similarity of the names	Patient did not receive any doses	THE PRODUCTS OF LAMICTAL 50, 100, 25 MG AND 200 MG ARE ALMOST IDENTICAL IN SOUND AND SPELLING TO LAMISIL 25 MG. THESE TWO MEDICINES CAN BE GIVEN ONE OF ANOTHER ERRONEOUSLY. MEDICATION ERROR
ISR Number: 4294853	UNK	2/20/2003	US	Lamisil	Lamictal	None reported	Rash	This report describes the occurrence of a dispensing error, rash, headache and neck pain in an adult male who was prescribed terbinafine (Lamisil) tablets (dosage unknown) for an antifungal condition. He received lamotrigine (Lamictal- unknown formulation) tablets at an unknown dosage for 90 days secondary to a prescription dispensing error. The patient developed a rash, headache and neck pain. His past medical history included eczema. The dispensing error was revealed after the patient had received lamotrigine for 90 days and had returned to the pharmacy for a refill. A biopsy was performed on [REDACTED]. The dermatologist did not think the rash was related to a fungal problem. Lamotrigine was discontinued and the headache resolved. The rash remained unresolved at the time of reporting.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4295385	50	6/3/2003	US	Lamisil	Lamictal	None reported	Rash	<p>This case was reported by a physician and described the occurrence of dispensing error and increased blood pressure in a 50-year-old female patient who received Lamotrigine (Lamictal) tablets, which were mistakenly dispensed instead of prescribed terbinafine (Lamisil). The reporting physician is the patient's husband. Concurrent medical conditions included allergy. Concurrent medications included Multivitamin, Calcium, Vitamine E and Vitamin C.</p> <p>On 03 June 2003, the patient was given a prescription for Terbinafine (oral) 250mg; however, she received Lamotrigine (oral) at 200 mg daily secondary to a dispensing error. The patient never received terbinafine. Immediately after starting Lamotrigine, the patient experienced increased blood pressure, and five days later she experienced severe unilateral headache. A few weeks later, the patient developed a rash, flushing, peeling of fingers, insomnia, and somnolence. After a month she received samples from her physician, and noticed they were different from the original prescription. Treatment with Lamotrigine was discontinued. The events resolved in July 2003. In the reporting physician's opinion the events, which were considered to jeopardize the patient/ require intervention, were almost certainly related to treatment with Lamotrigine. On follow-up the physician reported a "dispensing error by pharmacy of a high dose of Lamictal without titration, mistakenly substituted for Lamisil".</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4322130	81	1-Feb-04	US	Lamictal	Lamisil	None reported	Minor Adverse events	Initial report received on 16 March 2004: This reporter is a physician who states that his wife was prescribed Lamictal (lamotrigine) for post-herpetic neuralgia and erroneously was dispensed oral Lamisil by her pharmacy. She ingested Lamisil in an escalating dosage, ultimately taking 750 mg daily during the final eleven days of therapy, when the error was realized. She had received a total of 26 days of Lamisil. Therapy with Lamisil was discontinued at this point. He reports she experienced weakness, lethargy and anorexia, with all events currently ongoing.
ISR Number: 4462686	UNK	4/1/1999	US	Lamisil	Lamictal	Picked name from drop down list on computer	Patient did not receive any doses	Order was written for Lamisal 25 PO QD-RN entered the order for Lamictal 25 mg PO QD into a separate data base (EMTEX), EMTEX does not link with the pharmacy computer (BDM) therefore the drug dispensed was Lamisal 250 mg - which was correct. Medication Error
ISR Number: 4527568	UNK	11/17/1997	US	Lamisil	Lamictal	Volume of workload	Unknown	medication error Lamictial dispensed as Lamisil

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4553152	43	11/1/2004	IRELAND	Lamisil	Lamictal	None reported	Hospitalization	<p>This case was reported by a physician and a pharmacist and described the occurrence of mania in a 43-year-old male patient who received lamotrigine (Lamictal) over a period of three months for a fungal infection. The patient's past medical history included allergy to sesame seeds and dystonic reaction with haloperidol. Concurrent medications included lithium salt. The patient had no history of depression. The patient was prescribed terbinafine (Lamisil) for a fungal infection, however was given lamotrigine in error. In [REDACTED] the patient started lamotrigine at an unknown dosing. The patient took lamotrigine at 50 mg daily for two months. In [REDACTED], the patient experienced mania with an elevated mood. The patient was hospitalised on an unknown date. Treatment with lamotrigine was stopped on [REDACTED]. The events resolved in [REDACTED]. This case was assessed as medically serious by GSK.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4561205	52	1/18/2005	US	Lamictal	Lamisil	None reported	No Adverse Event reported	Initial report received on 18 Jan 2005: This pharmacist reports a medication error in which a patient received Lamisil (terbinafine) instead of Lamictal (lamotrigine). He had taken Lamisil, 250 mg four times a day, for 30 consecutive days before noticing the difference at the pharmacy when he received his correct refill of Lamictal, of which he takes 1000 mg daily for seizures. He reports no untoward effects from the Lamisil, nor did he report any incidence of seizures during the course of therapy. He continues on Lamictal at present and did not have any further complaints.
ISR Number: 4566519	44	12/20/2004	US	Lamisil	Lamictal	misspelled drug as lamacil and looked like Lamictal	Patient did not receive any doses	Physician wrote order for Lamisil. Physician did not include indication with the order. Pharmacist entered order as Lamictal 100mg 2 1/2 tablets daily. This drug was non-formulary so the drug name would not appear on a list of drugs to choose from at order entry. Pharmacist not aware of diagnoses. Dose is unusual, requiring multiple tablets or splitting tablets. Dose is within the manufacturer's recommended dosing range. Nurse detected the error prior to administration. This is a scan of the order that the pharmacist saw at order entry. The drug was actually misspelled as "Lamacil" MEDICATION ERROR

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4580753	UNK	5/4/2004	US	Lamisil	Lamictal	None reported	Minor adverse even headache	This case was reported by a consumer and described the occurrence of a prescription dispensing error in a female patient who received Lamotrigine (Lamictal) tablets over a period of 1 Month. A physician or other health care professional has not verified this report. Concurrent medications included Prometrium and Estradiol. The patient was prescribed Lamisil. On [REDACTED], her prescription was filled with Lamotrigine (oral) 25 mg, in error. She took lamotrigine for one month and subsequently experienced a headache. When the error was discovered, treatment with Lamotrigine was discontinued. The outcome of the events is unknown.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4581835	80	2/15/2004	US	Lamictal	Lamisil	None reported	Minor adverse event	<p>This case was reported by a physician and described the occurrence of anorexia in his 80-year-old wife who received Lamotrigine (Lamictal) tablet over a period of 24 Days for post herpetic neuralgia. Concurrent medical conditions included allergy to sulfa drugs, atrial flutter, herpes zoster, hypertension and post herpetic neuralgia. Co-suspect medication included Lamisil. Concurrent medications included Neurontin, Atenolol, Tiazac, Ramipril, Coumadin and Zocor. On [REDACTED] the patient started Lamotrigine (oral) at See text daily. Immediate later, on [REDACTED], the patient experienced anorexia, lassitude, weakness and medication error. Treatment with Lamotrigine was discontinued. The events improved. The reporting physician considered the events were probably related to treatment with Lamotrigine. This is a dispensing error. The original prescription was written for Lamictal 25mg tablets. Take one tablet daily in week one and increase by one tablet daily each week until 4 tablets daily total daily dose is reached. The patient received Lamisil 250mg tablets. The patient had completed 3.5 weeks of therapy before her husband noticed the medication error. The Lamisil was discontinued approximately 6 days ago.</p>
ISR Number: 4619179	No patient involved	6/28/1996	US	Unknown	Unknown	Sound alike names	Patient did not receive any doses	REPORTER RELAYED HIS CONCERN FOR THE SOUND -ALIKE NAMES OF THESE TWO PRODUCTS (LAMISIL AND LAMICTAL). MEDICATION ERROR

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4658308	No patient involved	4/18/1997	US	Unknown	Unknown	Similarity of the names	Patient did not receive any doses	REPORTER RELAYED HIS CONCERNS FOR THE SIMILARITY IN NAMES BETWEEN THESE TWO PRODUCTS (LAMICTAL 25 MG AND LAMISIL 250 MG). THERE HAVE BEEN POTENTIAL DISPENSING ERRORS OCCURRING BETWEEN THESE TWO DRUGS. MEDICATION ERROR
ISR Number: 4673601	40	11/8/2004	Foreign	Lamictal	Lamisil	similar looking tablets	Minor adverse events	Initial report received on 08 Nov 2004. This case was reported by a senior policy analyst from the Canadian Health Authority, Biologics and Genetic Therapies Directorate during a Drug Information Association presentation. This woman with bipolar disorder was prescribed Lamisil instead of Lamictal. Contributing factors include the appearance of the drug (round white pill). The patient experienced a lack of efficacy and the patient became an insomniac. The outcome was unknown. Follow-up information received from the reporter on [REDACTED] She will not complete the ADR form as she was made aware of this event via an article. She does not have more information.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4677590	UNK	5/26/2005	US	Lamictal	Lamisil	None reported	Death	Initial report received from a pharmacist via the Marketed Health Products Directorate, Canada by Glaxo Smith Kline on 26 May 2005: This report described the occurrence of a medication error in a patient who received Lamictal unspecified tablet for an unknown indication. Co-suspect medication included Lamisil. On an unknown date, the patient started Lamictal. An unspecified time after starting Lamictal, the patient experienced a medication error involving Lamisil. The outcome was fatal.
ISR Number: 4734724	UNK	5/13/2005	Foreign	Lamictal	Lamisil	None reported	Death	This case was reported by pharmacist via the Marketed Health Products Directorate, Canada, and described the occurrence of a medication error in a patient who received Lamotrigine (Lamictal) unspecified tablet for an unknown indication. Co-suspect medication included Lamisil. On an unknown date, the patient started Lamotrigine. At an unspecified time after starting lamotrigine, the patient experienced a medication error involving Lamisil. The outcome was fatal. Upon follow-up on 12 July 2005, it was reported that the patient was elderly. GSK Case Number A0557600A is a duplicate of A0497589A. All future correspondence will be submitted to A0497589A.
ISR Number: 4838969	UNK	7/5/2005	Foreign	Lamisil	Lamictal	none reported	Intervention required	Wrong drug administered Drug prescribing error No adverse effect

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4887422	43	7/22/2005	Foreign	Lamictal	Lamisil	None reported	Minor Adverse event	Initial report received on 22 Jul 2005. This patient has taken Lamisil 250 mg six tablets daily for about a week and has experienced some nausea. Lamisil was inadvertently dispensed instead of Lamactil (lamotrigine). The patient has not experienced any seizures. Lamisil has been stopped. The outcome was not provided. The reporter considered the event to be related to Lamisil. Follow-up information received from a pharmacist on 20 Jan 2006: The reporter has confirmed that the patient had only taken two Lamisil tablets as a single dose before noting the error. The patient contacted the doctor and neurologist. The blood tests were normal and no further action was taken. The patient has recovered.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4916411	82	2/9/2004	Foreign	Lamisil	Lamictal	Computer selection Error	Death	Initial report received on 09 Feb 2004. This case was reported by the President of the Institute for Safe Medication Practices Canada (ISMP). An elderly patient died following a medication error. The patient was prescribed Lamisil for a fungal condition but was dispensed Lamictal (Glaxo-Smith-Kline) instead. A coroner's inquest is being held. Follow-up information received from a pharmacist on 18 Feb 2004: Regarding the cause of the event, the pharmacist could briefly provide what they have found. The order was handwritten as Lamisil 250 mg oral daily for 30 days. A pharmacy technician entered the order in the computer system by typing "lam" and she selected lamotrigine (Lamictal). The order was double-checked by a pharmacist, dispensed by another technician and also checked by another pharmacist. They all missed the error. The drug was dispensed in a traditional method (individual prescription for 30 days supply) to the nursing floor. The nurse missed the error when checking the drug labeled as Lamictal versus the original order of Lamisil. And the 24-hour MAR being generated by the pharmacy computer system did not help either. It did not seem there is a direct cause of the mix up of the drug in dispensing (between Lamisil and Lamictal). Follow up received 28 Jun 2004 from the QA specialist. The complaint has been closed. No further action will be taken. The suggestion by ISMP to modify some of the lettering in Lamisil to a "Tall Man" format, with bold and/or color, in order to better differentiate the product names is under evaluation by ISMP. GCRS# CAMI20040628145628 Follow-up report received on 16 Feb 2006 from quality assurance: The quality assurance evaluation report stated that the new label with tallman lettering has been approved and will be implemented with the product transfer occurring in 3Q2006

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4925487	UNK	3/1/2005	US	Lamictal	Lamisil	None reported	Unknown	This case was reported by a pharmacist and described the occurrence of medication error in a female patient who received Lamotrigine (Lamictal) tablet over a period of 60 Days. Co-suspect medication included Lamisil. Concurrent medications included No concurrent medication. On [REDACTED] the patient started Lamotrigine (oral) at 250 mg daily. At an unknown time after starting Lamotrigine, the patient experienced medication error and product complaint. The outcome of the events is unknown. The pharmacist reported that the patient was dispensed Lamictal instead of Lamisil. The patient received 250 mg every day for about 60 days.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4925578	44	1-Dec-04	US	Lamisil	Lamictal	None reported	Rash	This case was reported by a pharmacist and described the occurrence of dispensing error in a 44-year-old female patient who received Lamotrigine (Lamictal) unspecified tablet over a period of 1 Days for fungal infection. Co-suspect medication included Lamisil. Concurrent medications included No concurrent medication. On an unknown date, the patient started Lamotrigine (oral) at 200 mg daily. At an unknown time after starting Lamotrigine, on December 2004, the patient experienced dispensing error, rash, sore throat and product complaint. Treatment with Lamotrigine was discontinued. The events unresolved. Dispensing error resulted in patient taking one dose of Lamictal 200 mg instead of Lamisil 200 mg. Between 1 and 2 weeks after the dose of Lamictal, rash developed in patients arms, legs, and hands. She also developed a sore throat.
ISR Number: 4979075	UNK	1/5/2006	US	Lamictal	Lamisil	Similar names	Delayed treatment	There was an error involving Lamisil and Lamictal at a community pharmacy. A patient brought in a prescription for Lamictal 25 mg PO once daily. A 30-tab bottle of Lamisil 250 mg (terbinafine) was mistakenly pulled, labeled by pharmacy as lamictal 25 mg , and released that night to customer for use. The incorrect medication was given to the patient and used for about a month, Treatment delayed. Patient received the wrong medication. A contributing factor would be the similar names of the products. Medication Error

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 4984424	71	9-Jan-04	Foreign	Lamisil	Lamictal	Computer selection Error	Death	<p>This case was received from a physician via the Therapeutic Products Directorate, Canada, and described the occurrence of medication error in a 71-year-old female patient who received Lamotrigine (Lamictal) unspecified tablet over a period of 23 Days for drug use for unknown indication. Co-suspect medication included Levaquin. Concurrent medications included docusate sodium, Humulin-R, metronidazole, nicotine and simvastatin. On an unknown date, the patient started Lamotrigine. On [REDACTED], the patient experienced fever, rash, blisters, facial edema, oral edema, leukocytosis, pruritus and a medication error involving Levaquin. The patient was treated with Burrow's solution, magic mouthwash, diphenhydramine and Fucidin. The outcome was fatal. Follow-up information was received from Health Canada on 21 April 2006. Health Canada provided information that had been received from a pharmacist and included the following: The patient was reported to be 71 years old at the time of the event; year of birth was 1[REDACTED]. The patient received Lamictal in error instead of Lamisil. Lamisil had been prescribed, but was entered into the computer in error as Lamictal. The patient started Lamictal at 250 mg daily, two and one-half 100 mg tablets, on [REDACTED]. Co-suspect medication was reported as Levofloxacin (Levaquin) 250 mg / 50 mL injection, 250 mg IV daily from [REDACTED] for suspected pneumonia. Concurrent medications included Humulin R Insulin, Simvastatin, Docusate Sodium, Metronidazole, and Nicotine patch. The patient had a history of right-sided CVA. Concurrent medical conditions included being a smoker, hypertension, dyslipidemia, and diabetes mellitus. At an unknown period of time after starting Lamictal, the patient experienced a rash on her abdomen, chest and face, a fever, pruritis, swollen face, lips, and tongue, and blisters on her forearms, thighs and lips. Treatment medications included Burosol twice daily beginning on [REDACTED], Diphenhydramine 25 - 50 mg orally, every six hours as needed beginning on [REDACTED], Diphenhydramine 12.5 - 25 mg IV every six hours as needed beginning on [REDACTED]. Fucidin cream twice daily beginning on [REDACTED], and Magic Mouthwash beginning on [REDACTED]. The pharmacist assessed the events as life threatening and the patient died on an unknown date in</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5081507	UNK	1-Feb-06	US	Lamisil	Lamictal	Illegible Prescription	Patient did not receive any doses	The pharmacy dispensed Lamictal 100 mg x 2 182 tablets rather than Lamisil 250 mg tablets as prescribed. The hard copy of the prescription was scanned into the computer and the scanned copy of the prescription was not clear. Medication Error

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5086564	53	4-Jan-06	US	Lamisil	Lamictal	None reported	Minor Adverse Event	<p>This case was reported by a physician, via a sales representative, and described the occurrence of dispensing error in a patient who received Lamotrigine (Lamictal) in error. Co-suspect medication included Lamisil. On an unknown date, the patient was prescribed Lamisil at unknown dosing. The pharmacy dispensed Lamictal 200 mg in error. At an unknown time after taking Lamictal, the patient experienced swollen glands. At the time of reporting, the outcome of the events was unknown. Follow-up was received from the physician on [REDACTED].</p> <p>The physician reported that the patient was a 53-year-old female. The physician reported that the patient never received Lamisil, she only received Lamictal due to a pharmacy dispensing error. The patient started Lamictal on approximately [REDACTED]. On [REDACTED] the patient experienced severe cervical lymphadenopathy and on [REDACTED], the patient experienced anemia (hemoglobin 11.8), neutropenia (WBCs 2.6), and increased platelets (platelet count 503). Lamictal was discontinued on [REDACTED] and the events were resolved completely by [REDACTED].</p> <p>The physician did not consider the events to be serious. This report has been assessed as medically serious by GSK. The physician thought that the events were related to Lamictal and commented that the events were due to the patient being on Lamictal 200 mg which was erroneously given to her.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5158710	UNK	10/25/2006	US	Lamisil	Lamictal	None reported	Hospitalization	<p>This case was reported by a consumer and described the occurrence of medication error in a male patient who received Lamotrigine (Lamictal) tablet over a period of 1 weeks for an unknown drug indication. A physician or other health care professional has not verified this report. Concurrent medications included No concurrent medication.</p> <p>On [REDACTED] the patient started Lamotrigine (oral) at 200 mg daily. At an unknown time after starting Lamotrigine, the patient experienced medication error, drug prescribing error, rash, vomiting, headache, fever and dehydration. The patient was hospitalised. Treatment with Lamotrigine was discontinued. At the time of reporting, the events were unresolved. Consumer reported that her son-in-law was mistakenly prescribed Lamictal 200 mg once a day instead of Lamisil for a toenail fungal infection. The prescription was filled by the pharmacist. The patient took Lamictal for ten days before he was hospitalized for one week from [REDACTED] to [REDACTED] due to high temperatures of 105.5, rash to his arms and legs, vomiting, and headache. According to the consumer, at the time of reporting the physician was considering re-hospitalization due to continued vomiting, fever, and dehydration. No further information available.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5250122	19	1-Jan-06	US	Lamisil	Lamictal	None reported	Hospitalization	<p>This case was reported by a physician and described the occurrence of rash in a patient who inadvertently received Lamotrigine (Lamictal) unspecified tablet instead of the prescribed terbinafine (Lamisil) for a fungal nail infection. On an unknown date, the patient inadvertently started Lamotrigine (oral), 250 mg twice daily, instead of the prescribed terbinafine (Lamisil) [dispensing error]. At an unknown time after starting Lamotrigine, the patient experienced a rash. Treatment with Lamotrigine was discontinued. The patient presented to the Emergency Room (ER) and was treated with steroids and was later released. At the time of reporting, the outcome of the event was unknown. Follow-up information received via a phone call from the reporting physician on [REDACTED] indicated that the patient was prescribed Lamisil 250 mg daily in [REDACTED]. The prescription was filled as Lamictal 100 mg -two and 1/2 tablets daily rather than the prescribed Lamisil dose. The patient took the Lamictal daily for two weeks before a rash occurred on [REDACTED]. Lamictal was discontinued. The patient also experienced a burning sensation (NOS). The patient was seen at the emergency room and treated with oral Prednisone. The physician also reported that a Dermatologist biopsied the rash today, and determined it was drug related. The physician reported that she is "almost certain" that the event is related to Lamictal. The outcome of the event is unknown. Follow-up was received from the physician on [REDACTED]. The patient had been originally prescribed Lamisil, 250 mg tablets, 2 tablets per day but was given Lamictal instead. The physician spoke with the pharmacist about the erroneous administration. The event resolved on [REDACTED].</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5251056	UNK	8/17/2006	US	Lamisil	Lamictal	None reported	Patient did not receive any doses	This case was reported by a pharmacist via the USP Medication Errors Reporting Program and described the occurrence of medication error in a male patient who received Lamotrigine (Lamictal) tablet in error. Co-suspect medication included Lamisil. On an unknown date, the patient was dispensed 2.5 tablets of Lamictal 100 mg instead of Lamisil 250 mg as prescribed. The error was caught by the pharmacist during a conversation with the patient, who never took a dose of the incorrect product. The pharmacist stated a hard copy of the prescription had been scanned into the computer, and the scanned copy was not clear. At the time of reporting, the outcome of the event was unknown.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5308679	70	21-Apr-07	US	Lamisil	Lamictal	None Reported	DEATH	<p>This case was reported by a physician and described the occurrence of death nos in a 70-year-old male patient who received Lamotrigine (Lamictal) tablet over a period of 6 weeks due to a dispensing error. Concurrent medications included midodrine hydrochloride (Proamatine). On [REDACTED] the patient started Lamotrigine (oral), unknown dosing. Treatment with Lamotrigine was discontinued. On [REDACTED], post-treatment the patient experienced death nos. The physician considered the events to be life threatening. The reporting physician considered the events were possibly related to treatment with Lamotrigine. The patient died on [REDACTED] cause of death is unknown. It is unknown whether an autopsy was performed. The physician reported that a patient who was prescribed terbinafine (Lamisil) was provided Lamictal instead. According to the patient's wife, he took the Lamictal for forty days before the pharmacy realized that the incorrect medication was dispensed. Lamictal was discontinued at the beginning of April.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5443355	UNK	28-Aug-07	US	Lamictal	Lamisil	None reported	no adverse event reported	<p>This case was reported by a physician, a psychiatrist and described the occurrence of drug dispensing error in a male patient who received Lamotrigine (Lamictal) tablet over a period of 1 days for an unknown drug indication. Concurrent medications included fluoxetine hydrochloride (Prozac) and aripiprazole (Abilify). On [REDACTED] the patient started Lamotrigine (oral) at 200 mg twice per day. Same day later, on [REDACTED], the patient experienced drug dispensing error. The physician considered the event to be clinically significant (or requiring intervention). Treatment with Lamotrigine was discontinued. At the time of reporting, the outcome of the event was unknown. The psychiatrist reported that a drug dispensing error occurred at the pharmacy but did not mention an adverse event at the time of the reporting. The psychiatrist stated that Lamictal 200 mg was dispensed in error instead of the unknown medication written on the prescription. The patient took 400 mg of lamictal during a 24 hour period. No adverse events have occurred.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5491989	53	6/5/2007	FRANCE	Lamisil	Lamictal	None reported	Hospitalization	<p>This case was reported by the French regulatory authority (AFSSaPS number RN20070024) and described the occurrence of toxicoderma in a 53-year-old female patient who received by error lamotrigine (Lamictal) unspecified tablet over a period of 37 days. Concurrent medical conditions included lumbar pain and onychomycosis. Concurrent medications included paracetamol + caffeine + dextropropoxyphene (Propofan) and paracetamol (Efferalgan) from [REDACTED] to [REDACTED]. The patient had been treated for about 2 years with terbinafine (Lamisil) at 250 mg daily for onychomycosis. On [REDACTED], Lamotrigine 200mg (Lamictal) was dispensed by error to the patient instead of terbinafine (Lamisil). On that same day, the patient started treatment with lamotrigine at 200 mg daily. Approximately 10 days after starting lamotrigine, on [REDACTED], the patient presented with fever at 39-40 Celsius degrees and general malaise. On [REDACTED], the patient developed maculopapulous eruption on thigh, which spread afterwards over the entire body. Then the patient developed face edema. On [REDACTED], the patient was hospitalized. At the admission, the patient presented diffuse eczematous eruption with some localized purpuric lesions and fever at 39 Celsius degrees. Blood analysis evidenced hyperlymphocytosis with hyperbasophile lymphocytes and a mild hepatocellular injury. There was neither hypereosinophilia nor adenopathy. On that same date, [REDACTED], treatment with lamotrigine was discontinued.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5491989 (Continued)	53	6/5/2007	FRANCE	Lamisil	Lamictal	None reported	Hospitalization	<p>On [REDACTED], the patient's condition worsened with occurrence of cheilitis and conjunctivitis. On the following days, the patient's condition was stabilized. It was reported that at the beginning of the hospitalization, after restarting treatment with paracetamol (Efferalgan), skin eruption was aggravated. However, the responsibility of paracetamol was ruled out because of the chronic paracetamol + caffeine + dextropropoxyphene (Propofan) intake. At the time of reporting ([REDACTED]), the events were unresolved. The regulatory authority reported that the events were possibly related to treatment with lamotrigine, according to the French method of imputability. The patient was 54-year-old. Follow-up information received on [REDACTED]: Skin biopsy evidenced superficial lymphocyte dermal infiltrate, purpura, spongiosis and local alteration of epidermal basement membrane (local skin lesion). The patient was treated with corticoids and the evolution was favourable. The patient was hospitalized from [REDACTED] to [REDACTED]. Skin appearance recurred during corticoids weaning (at 5 mg per day) in [REDACTED]. On [REDACTED], corticoids dose were increased up to 60 mg daily because of erythroderma, fever (body temperature at 39 Celsius degrees) and shiver. There was no argument for infectious cause. The diagnosis of toxicoderma reactivation of drug rash with eosinophilia and systemic symptoms type during corticoids dose decrease was posed. After restarting corticoids, the evolution was favourable.</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
ISR Number: 5749229	58	4/24/2008	US	Lamisil	Lamictal	Computer selection Error	Delayed treatment and Minor Adverse events	I saw a podiatrist at the request of Aetna Rx Home because they didn't want to fill my Lamisil though I was loosing toenails to a fungus. I had to wait and have the fungus test, took several weeks, and then the podiatrist faxed the fungus report along with an electronic medication call Lamictil 200mg. He said his pointer pointed to the wrong drug. I was supposed to be on fungus meds, called Lamisil. Instead he prescribed an anti-seizure and bi-polar medication to me by mispointing to the wrong med. I took three weeks, and in those three weeks, my toes not only did not get better, but my vision was very bad and blurred, I lost a lot of weight and became dehydrated. I had a huge increase in my already treated insomnia. I laid awake all night one night just itching and scratching, other nights I was just restless. Many bruises showed on my body and I broke a toe stumbling around in another world. I was in a mental fog, I couldn't and still cannot type without a lot of errors. I stumbled a lot and broke a toe. I even had suicidal thought. I was becoming bipolar and didn't know it. My family and friends noticed and commented on my behaviour. I was teary eyed and cried. This is not like me. None of it is. I had symptoms of TIA, chest pain, blurred vision with swollen eyes, itching, insomnia, bruising, confrontational behavior. Totally not like me. I lived in a fog all along for three weeks until it was noticed.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number A0062370A	UNK	3/3/1998	US	Lamisil	Lamictal	None reported	Rash	Physician reported that due to a dispensing error, several patients had received oral Lamotrigine (Lamictal) instead of oral terbinafine and developed a rash.
GSK Reference Number A0083666A	39	2/12/1999	US	Lamisil	Lamictal	None reported	Unknown	A 39 year old female received terbinafine rather her prescribed medicatin or oral Lamotrigine (Lamictal). She noticed the pharmacy dispensing error prior to ingesting the terbinafine. Published: Vossler DG. Another erroneous substitution or Lamisil for Lamictal. J Epilepsy 1998;11:389. Vosslet DG. Another erroneous substitution of Lamisil for Lamictal. J Epilepsy 1998;11:389.
GSK Reference Number A0091987A	UNK	5/5/1999	US	Unknown	Unknown	None reported	Minor adverse event	An adult male reported that he received Lamotrigine (Lamictal) tablets instead of terbinafine (Lamisil) tablets as a result of a dispensing error and developed mild joint pain. Lamotrigine was discontinued and his symptom resolved.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number A0134927A	44	12/9/2000	US	Lamictal	Lamisil	None reported	Hospitalization	A physician reported that a 44 year old male was prescribed Lamotrigine (Lamictal) tablets, but received terbinafine (Lamisil) tablets due to a prescription dispensing error. The patient developed nausea and vomiting and was evaluated in the emergency room. Terbinafine was discontinued and Lamotrigine was restarted. Upon follow-up, the physician reported that the events were considered serious because the patient required an emergency room visit. Lamotrigine was restarted and was titrate upward toward the patient's therapeutic dose. The events resolved after the ER visit. In the physician's opinion, the events were not related to Lamotrigine.
GSK Reference Number A0499687A	50	2/24/2004	US	Lamisil	Lamictal	None reported	Unknown	This case was reported by a consumer and described the occurrence of dispensing error in a 50-year-old male patient who received Lamotrigine (Lamictal) unspecified tablet over a period of 30 Days. A physician or other health care professional has not verified this report. The patient's past medical history included microalbuminuria, neuropathy and retinopathy. Concurrent medical conditions included type 1 diabetes. On an unknown date, the patient started Lamotrigine (oral) at 100 mg daily. At an unknown time after starting Lamotrigine, the patient experienced dispensing error. The outcome of the event is unknown. The patient reported that he was dispensed Lamictal in place of Lamisil

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number A0598996A	UNK	3/20/2006	US	Lamictal	Lamisil	None reported	No Adverse Event reported	A patient of unknown age took Lamisil tablets for one month instead of Lamictal tablets. No adverse events reported
GSK Reference Number A107563A	44	11/12/1999	US	Lamisil	Lamictal	None reported	Rash	A 44 year old male reported he was given a prescription for Lamisil and instead received Lamotrigine (Lamictal) tablets and developed a deep red sunburn like rash that was described as a hypersensitivity rash on his right side from his waist to the middle of his chest and from this right arm pit down the inside of his arm. He also developed a nodule under his right breast with four finger-like raised areas that were about the size of a pencil that ran from the nodule down to his stomach area. He had several tests performed and recalled that hepatic test were normal. Lamotrigine was discontinued, and the rash resolved in approximately four to five weeks after onset. The nodules did not fully resolve for two months post-onset. In follow up the patients noted that he is more sensitive to the sun since the event occurred.
GSK Reference Number A125845A	UNK	8/10/2000	US	Lamisil	Lamictal	None reported	minor adverse events	A pharmacist reported that a female was prescribed terbinafine (Lamisil) tablets but received Lamotrigine (Lamictal) tablets as a result of a dispensing error. She received Lamotrigine for one week and developed stomach upset and "generally not feeling well." Lamotrigine was discontinued.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number B0039866A	31	6/27/1996	Foreign	Lamisil	Lamictal	None reported	Intervention	A physician reported that a healthy 31 year old male received Lamotrigine (Lamictal) for 2 months and experienced asymptomatic atrial fibrillation. The patient was supposed to have been receiving terbinafine (Lamisil) but was given Lamotrigine by mistake. The patient was airforce pilot and the vent and mistake were discovered during a routine medical check up. Lamotrigine was withdrawn and the event resolved.
GSK Reference Number B0042701A	55	10/8/1996	Foreign	Lamisil	Lamictal	None reported	Minor adverse events	A physician reported that a 55 year old female received Lamotrigine (Laictal) 50 mg in error (should have been Lamisil). The female experienced depression, mood swings, weepiness and tiredness after Lamotrigine was withdrawn.
GSK Reference Number B0042877A	54	11/11/1996	Foreign	Lamisil	Lamictal	None reported	Minor adverse events	A regulatory authority reported that 54 year old female patient received oral Lamotrigine (Lamictal) for six months as the result of a prescription error. Terbinafine (Lamisil) should have been prescribed. After drug withdraw, she developed severe depression and lassitude and lassitude with early morning exacerbations. The symptoms were improving at the time of reporting.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number B0324088A	24	3/2/2004	Foreign	Lamisil	Lamictal	None reported	Rash	This case was reported by a physician and described the occurrence of tiredness in a 24 year-old male patient after he received Lamotrigine (Lamictal) over a period of 3 weeks. Concurrent medical condition included fungal infection on feet. On an unknown date, the patient's pharmacist dispensed Lamotrigine (oral) at 25 mg daily instead of Lamisil 250 mg tablets. The patient had been taking Lamotrigine tablets for approximately three weeks before his pharmacist notified him of the error. The patient felt tired and angry whilst on lamotrigine. The patient also noted a rash on his feet. It was hard to distinguish between the rash and the fungal infection on his feet. The patient's doctor recommended that he should wait 14 days before commencing treatment with Lamisil. Treatment with Lamotrigine was discontinued and the symptoms resolved. The reporting physician stated that "the rash was what was to be treated for with Lamisil".

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number B0389298A	Unknown	7/27/2005	Unknown	Lamisil	Lamictal	Unknown	Unknown	Unknown
GSK Reference Number B0405699A	60	3/22/2006	US	Lamisil	Lamictal	None reported	No Adverse Event reported	No adverse event reported

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
GSK Reference Number B0466795A	57	5/4/2007	Foreign	Lamisil	Lamictal	None reported	delay in treatment	This case was reported by a pharmacist and described the occurrence of wrong drug administered in a male patient who received Lamotrigine (Lamictal) tablets over a period of four weeks for fungal infection of the nail. On a unknown date, the patient started Lamotrigine (oral) at 200 mg daily. The patient was administered the wrong drug. He was meant to receive Lamisil (250 mg) for the treatment of fungal nail infection. Verbatim text: A pharmacist called to report that a patient had received Lamictal, 200 mg daily for 4 weeks in error, for the treatment if a fungal nail infection. The patient was meant to be receiving Lamisil.
GSK Reference Number D129353	UNK	7/12/2000	US	Lamisil	Lamictal	Similar sounding names	Intervention	A doctor's nurse called in a prescription which was supposed to be for Lamisil, and it was taken by the pharmacist, myself, as Lamictal. MedWatch staff member, David Konigstein, RPh, contacted the reporter for additional information. The product was prescribed by a dermatologist. The reporter heard Lamictal and questioned the nurse, "Are you sure it's :amictal?" and she replied yes. This occurred 3 months ago. This prescription was dispensed as Lamictal. The rporter had no idea anything was amiss until recently. When the patient's mother brought it to the attention of the doctor. The nurse now states she did not call it in as Lamictal. The young man is undergoing some testing. The reporter has no additional details about any adverse events, if any that occurred.

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
FDA Reference number MSB 98-00722	Unknown	12/31/1997	US	Lamisil	Lamictal	Similar names	Unknown	A dispensing error because Lamisil was ordered but Lamictal was dispensed for a 1-month period. The reporter feels that serious adverse effects are possible if the two products are switched. He feels the names are "too close for comfort".
4619260	No patient involved	5-Aug-96	US	Lamisil	Lomotil	Similar names	Complaint names are similar	Report of look-alike and sound alike drug names: Terbinafine-Terfenadine Lamisil-Lomotil medication error
4619252	No patient involved	16-Aug-96	US	Lamisil	Lomotil	Similar names	Complaint names are similar	Lamisil can easily e confused for Lomotil because both drug names sound alike and , when written in cursive, look alike. This could lead to a mix-up. medication error
3308960	16	19-Jul-99	US	Ketoconazole	Lamisil	None reported	Hospitalization	THE PRESCRIPTION WAS FOR BETOCONAZOL AND WAS FILLED INCORRECTLY WITH LAMISIL. THE PATIENT TOOK LAMISIL FOR 5 OR 6 DAYS AND DEVELOPED DIZZINESS, NAUSEA, HEADACHE, AND TREMORS. THE PATIENT WENT TO AN EMERGENCY ROOM AND WAS DIAGNOSED AS HAVING AND ADR TO LAMISIL AND IT WAS DISCONTINUED.
3346204	70	8-Sep-99	US	Lamisil	Lariam	No reported	No adverse events	MEDICATION ERROR PATIENT WAS PRESCRIBED "LAMISIL", BUT WAS DISPENSED LARIAM. PATIENT TOOK LARIAM 250MG, 1PO QD x 30 DAYS. ****DRUG MALADMINISTRATION****

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
3200611	82	Unknown	US	Lamisil	Lariam	None Reported	Intervention Required	<p>AN 82 YEAR OLD FEMALE PATIENT DEVELOPED DISABLING HEARING LOSS, CONFUSION, AGITATION, ATAXIA, DIZZINESS AND SPEECH DIFFICULTY FOLLOWING THE ADMINISTRATION OF LARIAM (MEFLOQUINE) IN ERROR. THE PATIENT HAD ONYCHOMYCOSIS. THE PATIENT WAS PRESCRIBED LAMASIL (TERBINAFINE) 250 MG PER DAY. A DISPENSING ERROR RESULTED IN THE PATIENT BEING GIVEN LARIAM INSTEAD. AFTER THE PATIENT HAD TAKEN LARIAM EACH DAY FOR 10 DAYS, SHE EXPERIENCED CONFUSION, AGITATION, ATAXIA, DIZZINESS SPEECH DIFFICULTIES AND HIGH-FREQUENCY HEARING LOSS. THE ERROR WAS NOTED AFTER 2 MONTHS, LARIAM 250 MG HAD BEEN TAKEN EACH DAY FOR A TOTAL OF 61 DAYS (TOTAL DOSE 15250 MG). 1 YEAR LATER, THE PATIENT CONTINUED TO EXPERIENCE MILD RESIDUAL HEARING LOSS BUT ALL OTHER SYMPTOMS HAD RESOLVED. THERE WAS INSUFFICIENT INFORMATION AVAILABLE TO ENABLE COMPANY ASSESSMENT FOR THE CONFUSION, AGITATION, ATAXIA, DIZZINESS AND SPEECH DIFFICULTY. THIS WAS TAKEN FROM: DRUG OVERDOSES WITH ANTIMALARIAL AGENTS: PRESCRIBING AND DISPENSING ERRORS. LOBEL H, COYNE P, ROSENTHAL P. JAMA 4 NOV 98; VOL 280 (17); 1483. ADDITIONAL PATIENTS FROM THIS ARTICLE ARE COVERED UNDER MCNS 113209 AND 113216</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
3569032	56	03/1997	US	Lamisil	Lariam	None Reported	Permanent Harm	<p>A 56 YEAR OLD MALE PATIENT EXPERIENCED LOSS OF LEG CONTROL AND SHORT TERM MEMORY LOSS WHICH CAUSED DISABILITY AND TEMPORARY BLINDNESS DURING THE USE OF LARIAM(MEFLOQUINE) FOR A TOE FUNGAL INFECTION. THE PATIENT HAS NO KNOWN ALLERGIES TO MEDICATION AND DOES NOT SMOKE OR DRINK ALCOHOL. 1998 (EST.): THE PATIENT WAS MISTAKENLY ADMINISTERED LARIAM BY A HOSPITAL PHARMACY FOR A FUNGAL INFECTION OF THE TOE. HE STARTED LARIAM 250 MG, BID, PO FOR APPROXIMATELY 6 WEEKS. DURING AND FOLLOWING THE LARIAM OVERDOSE THE PATIENT FELT VERY SICK. HE EXPERIENCED PROBLEMS WITH HIS LEGS WHICH IMPAIRED HIS MOBILITY AND HIS SHORT TERM MEMORY WAS NOTICEABLY IMPAIRED. THE PATIENT HAD TO STOP WORKING BECAUSE OF HIS IMPAIRED MOBILITY AND SHORT TERM MEMORY IMPAIRMENT. LARIAM WAS DISCONTINUED. UNKNOWN DATE: FOLLOWING THE LARIAM OVERDOSE THE PATIENT CONTACTED THE POISON CONTROL CENTRE AND A NUMBER OF UNSPECIFIED TESTS WERE PERFORMED (RESULT UNKNOWN). ██████████ (EST.): THE PATIENT ALSO EXPERIENCED AN EPISODE OF TEMPORARY BLINDNESS UPON AWAKENING ONE MORNING</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
3569032 (continued)	56	03/1997	US	Lamisil	Lariam	None Reported	Permanent Harm	<p>██████████ IT WAS STATED THAT THE PATIENT WAS APPROACHING TOTAL SHUT DOWN AND SLOWLY DYING. AT THE TIME OF THE REPORT THERE WAS INSUFFICIENT INFORMATION TO COMMENT ON THE OUTCOME OF THE EVENTS. THE REPORTER WAS THE PATIENT'S UNCLE. FURTHER INFORMATION RECEIVED ON ██████████ INDICATED NEW EVENTS OF BRAIN DAMAGE (EXCLUDING PERINATAL) AND MENTAL DISTRESS AND THERAPY DATES. EARLY ██████████: THE PATIENT BEGAN TAKING LARIAM, PREVIOUSLY REPORTED AS 1998 (EST.). DATE UNKNOWN: THE PATIENT HAS PERMANENT INJURY INCLUDING, BUT NOT LIMITED TO, BRAIN DAMAGE AND MENTAL DISTRESS. AT THE TIME OF THIS REPORT, THE BRAIN DAMAGE AND MENTAL DISTRESS WERE PERSISTING. THE COMPANY CONSIDER THE BRAIN DAMAGE AND MENTAL DISTRESS AS MEDICALLY SIGNIFICANT. THE SECOND REPORTER STATED THAT THE PATIENT AND HIS WIFE WERE IN THE PROCESS OF TAKING LEGAL ACTION AGAINST THE HOSPITAL AUTHORITIES WHO SUPPLIED THE LARIAM. THIS FOLLOW-UP INFORMATION WAS DERIVED FROM INTERNET SITE ██████████</p>
3411669	No patient involved	25-Oct-99	US	Lamisil	Lomotil	Names are similar	Names are similar complaint Stocked wrong medication	<p>MEDICATIONS WITH SIMILAR NAMES - OBSTRETRICS REQUESTED THAT PHARMACY STOCK LAMICEL AND WE THOUGHT THEY MEANT LAMISIL, THE ANTIFUNGAL. BUT LAMICEL IS A SYNTHETIC OSMOTIC CERVICAL DILATOR USED TO INDUCE LABOT. COPY OF INFO ABOUT LAMICEL IS ATTACHED - MANUFACTURER IS MEROCEL IN MYSTIC CT. ***DRUG MALADMINISTRATION***</p>

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
3693521	UNK	25-Sep-00	US	Lamisil	Lanoxin	Placement on shelves	Patient never received dose	a customer of pharmacy placed an order for his Lamisil 250mg but received Lanoxin 0.25mg instead. The customer alerted us to the error and assured us no medication was taken. We replaced the med with the correct meds. The day of the incident #685 Rx's were filled. The error may have been do to the location of both drugs(side by side) and hectic work environment. Since the incident the drugs have been separated and new Epic system helps identify drugs through on screen ID drug maladministration
3977793	75	4-Sep-02	US	Lamisil	Lomotil	No reported	Patient never received dose	A prescription for Lamisil 250mg was generically dispensed for Lomotil DRUG MALADMINISTRATION

Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
4263087	67	25-Dec-03	JP	Baccidal norfloxacin Japan	Lamisil	No reported	Hospitalization	<p>Initial report received from the pharmacist on [REDACTED]: The pharmacy accidentally gave a patient Lamisil instead of Baccidal (norfloxacin). The patient experienced eyelid edema after four days of administration. The patient's outcome and the reporter's causality assessment were not provided. Follow-up information received from the physician on [REDACTED]. Patient initials provided. The patient received Lamisil 375 mg/d from [REDACTED]. The symptoms included eyelid edema, facial eczema and blar eye feeling. Thereafter, the patient was admitted with encephalitis. The outcome was not provided. The reporter considered the events to be related to Lamisil, though encephalitis was considered as not related. The seriousness criteria was changed from non-serious to hospitalisation. Follow-up information received on [REDACTED]: Patient details (age changed from 68 to 67 years) and concomitant medication provided. The patient was treated with Lamisil from [REDACTED] (previously reported as [REDACTED]). The events occurred on [REDACTED] (previously reported as [REDACTED]). The events resolved on [REDACTED] except for encephalitis. Follow-up information received on [REDACTED]: The reporter ruled out the occurrence of decreased visual acuity or visual field disorder, stating that the patient complained of difficulty seeing things due to eyelid edema.</p>

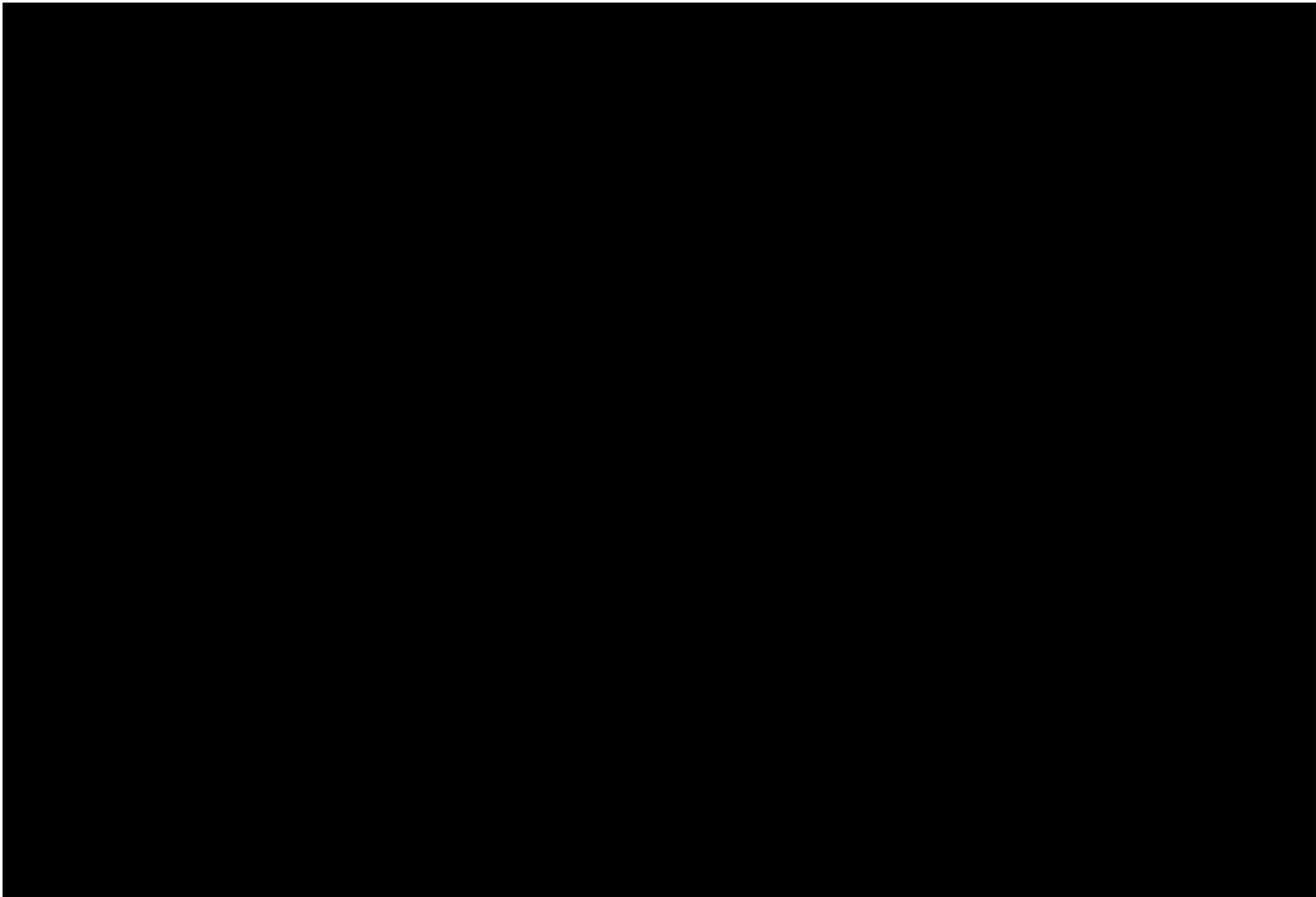
Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
5519010	UNK	31-Aug-07	US	Zyrtec	Lamisil	Busy Pharmacy	No outcome Reported	<p>Patient prescribed 3-month course of Lamisil. First fill of prescription was correct. On second fill, prior to leaving the pharmacy counter, he opened the prescription vial to verify that he had received the correct medication. The patient noticed that the tablets did not look that same as those he received on the first fill. The patient brought this discrepancy to the pharmacist's attention but unfortunately received the response "I would not have filled it if it wasn't correct." The patient took the pharmacist at her word, thinking that these tablets must be a generic version of Lamisil, and went home. The patient proceeded to take the tablets as prescribed. Near the end of the 30-day supply, the patient noticed that "Zyrtec" was imprinted on the tablet. The patient and his partner returned to the pharmacy to have the prescription corrected (note: the pharmacist on duty was the same as who dispensed the Zyrtec incorrectly a month before). While standing at the counter waiting for the pharmacist to finish correcting the prescription, the pharmacist angrily said "Are you going to look over my shoulder as I do this?" Pharmacist dispensed the correct Lamisil as ordered in a properly labeled vial, but also returned the remaining Zytec, for which the patient did not have a prescription, to the patient in an unlabeled vial. On second fill, prior to leaving the pharmacy counter, he opened the prescription vial to verify that he had received the correct medication. The patient noticed that the tablets did not look that same as those he received on the first fill. The patient brought this discrepancy to the pharmacist's attention but unfortunately received the response "I would not have filled it if it wasn't correct." The patient took the pharmacist at her word, thinking that these tablets must be a generic version of Lamisil, and went home. The patient proceeded to take the tablets as prescribed. Near the end of the 30-day supply, the patient noticed that "Zyrtec" was imprinted on the tablet. Unknown medication error</p>

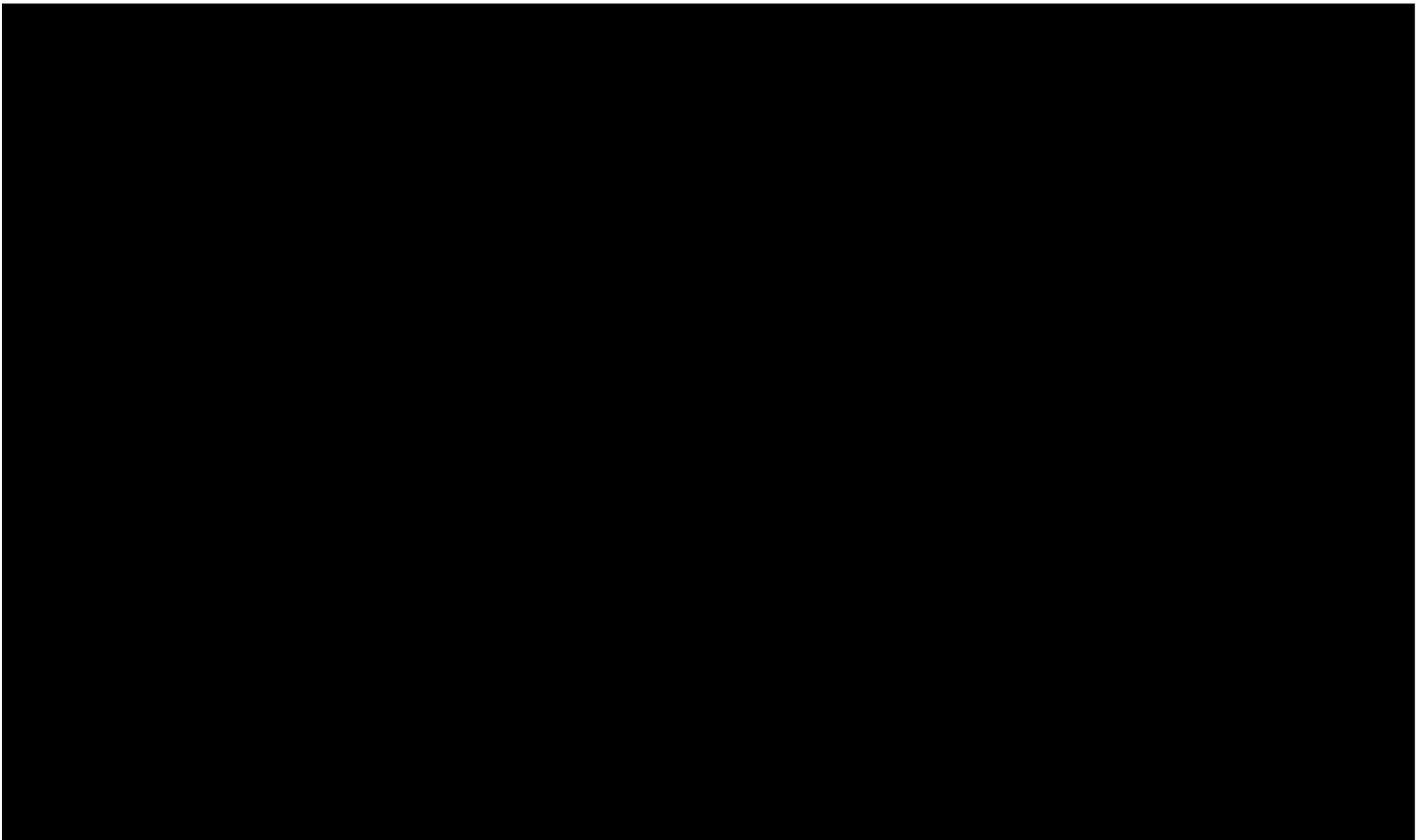
Reference Number	Age (Years)	Event Date	Location	Intended Drug	Dispensed Drug	Causality	Outcome	Narrative
5208626	UNK	26-Dec-07	AR	Tramadol spray	Lamisil spray	None reported	No outcome Reported	Initial report received from the patient on [REDACTED]: This patient was medicated with Tramal (tramadol) after a wrist fracture. On [REDACTED], the patient took 10 drops of Lamisil (terbinafine) spray instead of Tramal. At the time of reporting, no further information was available.

[REDACTED]

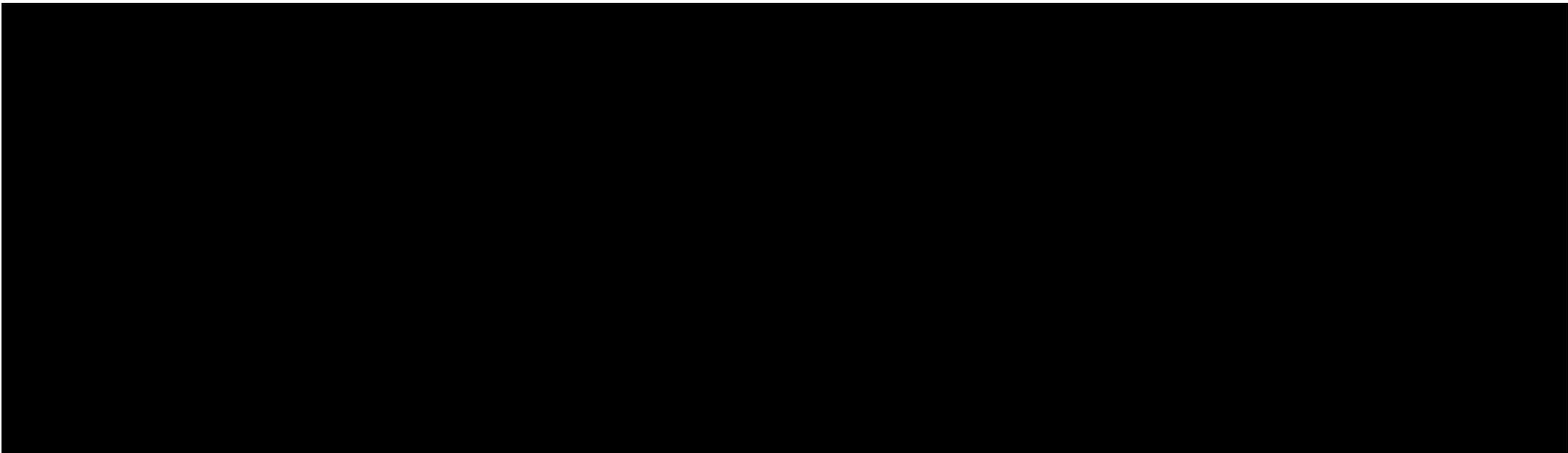
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
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/s/

Zachary A Oleszczuk
9/17/2008 08:23:15 AM
DRUG SAFETY OFFICE REVIEWER

Todd Bridges
9/17/2008 03:23:01 PM
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