CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-268

PROPRIETARY NAME REVIEW(S)

Department of Health and Human Services

Public Health Service

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Surveillance and Epidemiology

Date:	November 7, 2008
To:	Renata Albrecht, MD Division of Special Pathogens and Transplant Products
Through:	Todd Bridges, RPh, Team Leader Denise P. Toyer, Pharm.D, Deputy Director Carol Holquist, R.Ph., Director Division of Medication Error Prevention and Analysis (DMEPA)
From:	Denise V. Baugh, PharmD., BCPS, Safety Evaluator Division of Medication Error Prevention and Analysis (DMEPA)
Subject:	Response to Trade Name Rebuttal
Drug Name(s):	Coartem (Lumefantrine and Artemether) Tablets 120 mg/20 mg
Application Type/Number:	NDA# 22-268 (IND# 75,287)
Applicant:	Novartis Pharmaceuticals Corporation
OSE RCM #:	2008-1039

EXECUTIVE SUMMARY

The Division of Medication Error Prevention and Analysis first reviewed the name, Coartem, in OSE Review 2007-1691 dated April 14, 2008 and found the name unacceptable based on look-alike similarities with the name Comtan. In response, the Applicant submitted a rebuttal in support of the proprietary name, Coartem. Review of this information provides three main areas that will likely decrease the risk of confusion between Coartem and Comtan which are: pharmacies will not likely stock this product, the limited patient population who will use Coartem, and the likely use of the product in a hospital care environment. Based upon our re-evaluation of this information, we reverse our initial decision and find the proprietary name, Coartem acceptable.

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

1 INTRODUCTION

This memorandum is in response to a June 24, 2008 request from the Division of Special Pathogens and Transplant Products to reconsider the acceptability of the proposed proprietary name, Coartem.

2 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis found the proprietary name, Coartem unacceptable in the review OSE# 2007-1691 (dated April 14, 2008) based upon look-alike similarities with Comtan, in accordance with 21 CFR 201.10(c)(5).

In response to our objection, the Applicant submitted a rebuttal that focuses on the low likelihood of confusion that would lead to medication error between Coartem (Lumefantrine and Artemether) 120 mg/20 mg and Comtan (Entocapone) 200 mg. The rebuttal also stated the Applicant's willingness to commit to Phase 4 monitoring for medication errors related to the trademark, Coartem.

3 MATERIAL REVIEWED

We evaluated the trade name rebuttal prepared by the Applicant dated June 12, 2008 and we also reviewed our previous consult (OSE# 2007-1691) in which we expressed concerns with the potential for confusion of Coartem with Comtan.

4 DISCUSSION

We evaluated the information provided by the Applicant in support of reconsideration of the proposed name, Coartem. The three main areas that will likely decrease the risk of confusion between Coartem and Comtan are retail pharmacies will not likely stock this product, the limited patient population, and likely use of the product in a hospital care environment.

4.1 LOW INCIDENCE OF MALARIA IN THE U.S. AND LIKELY USE OF COARTEM IN THE INPATIENT SETTING

The Applicant states that the incidence of malaria in the U.S. over the past 10 years is approximately 1200 – 1600 cases per year. We also acknowledge that initiation of therapy for this product will likely occur in the hospital setting in the U.S. and that in this setting of care it is less likely an order will be transcribed with ambiguous directions for use such as 'UD' (as directed).

4.2 COARTEM DISTRIBUTION

The Applicant states that Coartem will be available only through 3 major wholesalers nationwide for distribution to a hospital or retail pharmacy within 24 hours, thus reducing the chance that Coartem could mistakenly be dispensed to a patient requiring Comtan. Additionally, Novartis plans to initially produce only (b) (4) units of Coartem. With more than 70,000 locations in the U.S. capable of dispensing prescription drugs, the likelihood of a pharmacy stocking this drug product is low.

Moreoever, given that malaria treatment should begin as soon as possible, communication would have to occur between the pharmacist and the physician, nurse and/or patient regarding the expected time of arrival of the medication. During this dialogue pertinent patient information would be conveyed alerting the pharmacist to the possibility of a misinterpretation of the order.

Thus, the above factors will help to minimize the likelihood for confusion between Coartem and Comtan in the usual practice setting.

5 CONCLUSIONS AND RECOMMENDATIONS

Our analysis of the data identified three main areas that will likely decrease the risk of confusion between Coartem and Comtan. These include the fact that pharmacies will not likely stock this product, the limited patient population, and the likely use of the product in a hospital care environment. Based upon our evaluation of this information, we reverse our initial decision and find the proposed proprietary name, Coartem acceptable.

We would be willing to meet with the Division for further discussion, if needed. Also, please copy the Division of Medication Error Prevention and Analysis on any correspondence to the sponsor pertaining to this consult. If you have any questions or need clarification, contact Darrell Jenkins, OSE Project Manager, at 301-796-0558.

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

/s/

Denise Baugh
11/7/2008 02:14:39 PM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
11/7/2008 02:25:03 PM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/7/2008 02:54:25 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE

DIVISION OF MEDICATION ERROR PREVENTION
OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
(DMETS; WO22, Rm. 4447)

DATE RECEIVED:	**DESIRED COMPLETION DATE:**	**OSE REVIEW #:** 2007-1691
August 1, 2007 **DOCUMENT DATE:** May 15, 2007	November 1, 2007	

TO: Renata Albrecht, MD
Division of Special Pathogen and Transplant Products
HFD-590

THROUGH: Linda Y. Kim-Jung, PharmD, Team Leader
Denise Toyer, Pharm.D., Deputy Director
Carol Holquist, RPh, Director
Division of Medication Error Prevention, HFD-420

FROM: Denise V. Baugh, Pharm.D., BCPS, Safety Evaluator
Division of Medication Error Prevention, HFD-420

PRODUCT NAME:	**IND SPONSOR:**
Coartem™ (Lumefantrine and Artemether) Tablets 120 mg/20 mg NDA# 22-268 (IND#: 75,287)	Novartis Pharmaceuticals Corporation

RECOMMENDATIONS:

1. The Division of Medication Error Prevention does not recommend use of the proprietary name, Coartem.

2. Container labels, carton and insert labeling were not submitted for review and comment. Please submit the labels and labeling when available for review and comment.

3. DDMAC finds the proprietary name, Coartem™, acceptable from a promotional perspective.

The Division of Medication Error Prevention would appreciate feedback of the final outcome of this consult. Please copy the Division of Medication Error Prevention on any correspondence forwarded to the sponsor pertaining to this review. We would be willing to meet with the Division for further discussion, if needed. If you have further questions or need clarifications, please contact Darrell Jenkins, OSE Project Manager, at 301-796-0567.

Division of Medication Error Prevention
Office of Surveillance and Epidemiology
HFD-420; WO22, Rm. 4447
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: April 14, 2008

NDA (IND)#: 22-268 (75,287)

NAME OF DRUG: **Coartem™**
(Lumefantrine/artemether) Tablets
120 mg/20 mg

IND HOLDER: Novartis Pharmaceuticals Corporation

I. INTRODUCTION:

This consult was written in response to a request from the Division of Special Pathogen and Transplant Products (HFD-590) for a review of the proprietary name, "Coartem", regarding potential name confusion with other proprietary and/or established drug names. The Division of Medication Error Prevention informed the Division that we noted the name refers only to one ingredient in the established name and that is in violation of 21 CFR 201.6(b). However, the Division requested we continue with the name review from a medication error perspective. Container labels, carton, and insert labeling were not submitted for review and comment at this time. The following product information was provided below.

PRODUCT INFORMATION

Coartem (lumefantrine and arthemer) is formulated in a fixed-dose combination tablet of lumefantrine 120 mg and artemether 20 mg. It is indicated for the treatment of malaria infections and is administered in the following manner:

Adults and children weighing 35 kg and above or older than 12 years of age:
At diagnosis, the patient receives four tablets, then four tablets 8 hours later, and four tabs twice daily (morning and evening) on each of the following two days (total course = 24 tablets).

Infants and children weighing 5 kg to < 35 kg and 12 years of age or less:
5 kg to < 15 kg: At diagnosis the patient receives one tablet, then one tablet 8 hours later, and one tablet twice daily on each of the following two days (total course = 6 tablets).

15 kg to < 25 kg: At diagnosis the patient receives two tablets, then two tablets 8 hours later, and two tablets twice daily on each of the following two days (total course = 12 tablets).

25 kg to < 35 kg: At diagnosis the patient receives three tablets, then three tablets 8 hours later, and three tablets twice daily on each of the following two days (total course = 18 tablets).

In countries where the product is registered and malaria is endemic, lumefantrine 120 mg and artemether 20 mg is available under the name, Coartem, while in other countries it is known as Riamet.

II. RISK ASSESSMENT

The medication error staff of the Division of Medication Error Prevention conducted a search of the internet, several standard published drug product reference texts[1,2] as well as several FDA databases[3,4] for existing drug name which sound-alike or look-alike to Coartem to a degree where potential confusion between drug names could occur under the usual clinical practice settings. A search of the electronic online version of the U.S. Patent and Trademark Office's Text and Image Database was also conducted[5]. The SAEGIS™ Online service [6] Pharma-In-Use database was searched for drug names with potential for confusion. An expert panel discussion was conducted to review all findings from the searches. In addition, the Division of Medication Error Prevention conducted three prescription analysis studies consisting of two written prescription studies (inpatient and outpatient) and one verbal prescription study, involving health care practitioners within FDA. This exercise was conducted to simulate the prescription ordering process in order to evaluate potential errors in handwriting and verbal communication of the name. Considering the collective findings, overall risk assessment is based on the results of a Failure Modes and Effects Analysis (FMEA) of the proprietary name, and is focused on the avoidance of medication errors. FMEA is a systematic tool for evaluating a process and identifying where and how it might fail. Additionally, The Division of Medication Error Prevention uses the clinical expertise of the Medication Error Staff to anticipate the conditions of the clinical setting that the product is likely to be used in based on the characteristics of the proposed product.

A. EXPERT PANEL DISCUSSION (EPD)

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

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[1] MICROMEDEX Integrated Index, 2007, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems.

[2] Facts and Comparisons, online version, Facts and Comparisons, St. Louis, Missouri.

[3] AMF Decision Support System [DSS], the Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-07, and the electronic online version of the FDA Orange Book.

[4] Phonetic and Orthographic Computer Analysis (POCA).

[5] www location http://www.uspto.gov/tmdb/index.html.

[6] Data provided by Thomson & Thomson's SAEGIS™ Online service, available at www.thomson-thomson.com

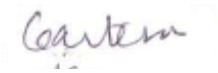
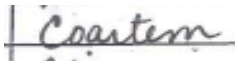
1. DDMAC did not have concerns with the name, Coartem, in regard to promotional claims.

2. The Expert Panel identified twenty-five (25) proprietary names that were thought to have the potential for confusion with Coartem. These products include Coactin, (b) (4) Caltrim, Cardene, Cardizem, Comtan, Cortan, Cortone, Cotrim, (b) (4) Loestrin 1.5/30, Losartan potassium, Cort-Dome, Cortef, Cortex, Cordran, Iocorten, Cortenema, Coumadin, (b) (4) Ciloxan, Avastin, Ceretec, Cortifoam, and Kao-tin. The Expert Panel also expressed concern that the name, Coartem, appeared to identify only one of its two ingredients which is not in accordance with 21 CFR 201.6(b).

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology:

Three separate studies were conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of Coartem with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 122 health care professionals (pharmacists, physicians, and nurses). This exercise was conducted in an attempt to simulate the prescription ordering process. An inpatient order and outpatient prescriptions were written, each consisting of a combination of marketed and unapproved drug products and a prescription for Coartem. These prescriptions were optically scanned and one prescription was delivered to a random sample of the participating health professionals via e-mail. In addition, the outpatient orders were recorded on voice mail. The voice mail messages were then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants sent their interpretations of the orders via e-mail to the medication error staff.

HANDWRITTEN PRESCRIPTION	VERBAL PRESCRIPTION
Outpatient RX: 	"Coartem 18 mg #90 – Take as directed."
Inpatient RX: 	

3. Results:

None of the interpretations of the proposed name overlap, sound similar, or look similar to any currently marketed U.S. products. See Appendix A for the complete listing of interpretations from the verbal and written studies. The majority of misinterpretations were misspelled/phonetic variations of the proposed name, Coartem.

C. MEDICATION ERROR STAFF SURVEY

1. Methodology

To assist in determining the overall risk of confusion of Comtan with the proposed proprietary name, Coartem, the safety evaluator conducted a poll of the Medication Error staff asking them to identify potential concerns about the orthographic and/or phonetic similarity of the Coartem and Comtam or Cotrim. The product characteristics (and writing samples) provided in the poll are listed in Appendix B.

2. Results

a. Comtan

In response to the reviewing safety evaluator's poll which asked, "Is the name Comtan convincingly similar to the proposed name, Coartem, such that practitioners would become confused at any point in the usual practice setting?" ten staff responded. Ten of the ten responses were 'yes'. The comments provided by the medication error staff are included in Appendix C. There was ten staff who responded to the follow up question, "If you believe the names are convincingly similar, could confusion between Comtan and Coartem conceivably result in medication errors in the usual practice setting?" Eight of the ten participants said 'yes'. (See Appendix D.)

b. Cotrim

In response to the reviewing safety evaluator's poll which asked, "Is the name Cotrim convincingly similar to the proposed name, Coartem, such that practitioners would become confused at any point in the usual practice setting?" ten staff responded. Four of the ten responses were 'yes'. The comments provided by the medication error staff are included in Appendix E. There was ten staff who responded to the follow up question, "If you believe the names are convincingly similar, could confusion between Cotrim and Coartem conceivably result in medication errors in the usual practice setting?" Three of the ten participants said 'yes'. (See Appendix F.)
These responses were further evaluated through FMEA.

D. SAFETY EVALUATOR RISK ASSESSMENT

In reviewing the proprietary name Coartem, twenty-five (25) names were thought to have the potential to sound or look similar to Coartem. These names include Coactin, (b) (4) Caltrim, Cardene, Cardizem, Comtan, Cortan, Cortone, Cotrim, Cortane, Loestrin 1.5/30, Losartan potassium, Cort-Dome, Cortef, Cortex, Cordran, Locorten, Cortenema, Coumadin, Cotazym, Ciloxan, Avastin, Ceretec, Cortifoam, and Kao-tin. The Expert Panel also expressed concern that the name, Coartem appeared to identify only one of its two ingredients which is not in accordance with 21 CFR 201.5(b). This concern was communicated to the Division. However, upon further evaluation, it was determined that because the individual ingredients in Coartem, artemether and lumefatrine, are not available in the U.S. nor commonly recognized in the U.S. healthcare community, it is anticipated that the risk of confusion with this name would be minimal if only one component was communicated in the proprietary name.

All twenty-five (25) names were thought to have some similarity to the proposed name, Coartem, and thus determined to present some risk for confusion. Failure Mode and Effects Analyses was then applied to determine if the proposed name, Coartem, could potentially be confused with any of the twenty-five (25) names and lead to medication error. This analysis determined that the name similarity between Coartem and twenty-four (24) of the drug names would unlikely result in medication errors. Sixteen (16) names lack significant look-alike and/or sound-alike similarities with Coartem, in addition to having differentiating product characteristics that may include: the product strength, dose, frequency of administration, route of administration, and dosage formulation. These names include Cardene, Cardizem, Cortone, Cortane, Loestrin 1.5/30, Cort-Dome, Cortef, Cordran, Cortenema, Coumadin, Cotazym, Ciloxan, Avastin, Ceretec, Cortifoam, and Kaotin.

No product information could be found for (b) (4) and Caltrim in commonly used references such as Micromedex, Facts & Comparisons online, Clinical Pharmacology or Redbook, thus these two names were not considered further. Cortan, Coactin and Locorten were discontinued from the market and no generic formulations of these products were found in independent research thus these three names were not considered further.

Cortex is a medical term referring to a portion of the brain and the Division of Medication Error Prevention cannot identify a scenario where the word ‘cortex’ can be confused with coartem leading to a medication error. Thus, this name was excluded.

Cotrim and Losartan were also considered to not pose a risk for confusion. Cotrim is a proprietary name used for a generic brand of sulfamethoxazole and trimethoprim. However, this brand name is no longer used by the manufacturer and therefore, confusion between Cotrim and the proposed name Coartem is unlikely. Additionally, Losartan does not have overlapping strengths with Coartem. Losartan is available in 3 different strengths which would need to be indicated on a prescription whereas Coartem could be dispensed without indication of strength.

The remaining name, Comtan, was determined to likely lead to medication errors with Coartem. See Table 1 (on page 7) and the discussion that follows.

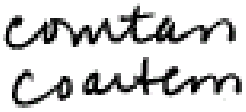
Table 1: Potential Sound-Alike/Look-Alike Names Identified for Coartem

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Coartem	Lumafantrine/artemether (COA5666) 120 mg/20 mg	Treatment of malaria infection: 6-dose regimen of 6, 12, 18 or 24 tablets depending on bodyweight, then subsequent doses are given at 8, 24, and 48 hours.	
Comtan	Entacapone Tablet: 200 mg	Adjunct treatment for Parkinson's Disease 200 mg with each dose of levodopa/carbidopa, up to a maximum of 8 tablets/day	LA

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)
*** Name pending approval. Not FOI releasable.

Comtan was identified as a name that looks similar to Coartem and thus cannot be safely co-marketed. Comtan is used as an adjunct treatment to levodopa/carbidopa to treat Parkinson's Disease. Comtan is available as a 200 mg tablet and is given with each dose of levodopa/carbidopa up to a maximum of 8 tablets/day.

Comtan and Coartem look similar when written because they share the first two letters ('Co') and end in letters that are not clearly distinguishable from each other ('an' vs. 'em'). Also, both of these names have an upstroke (lower case 't') in the same position of the names. This name pair also appears to be similar in length when written although Coartem is one letter longer.



Comtan and Coartem share some product characteristics. Both drugs share the same route of administration (oral) and dosage form (tablet). They are also available in a single strength (120 mg/20 mg vs. 200 mg) which means prescriptions for either of these products could be prescribed and/or dispensed without an indication of strength. Additionally both Comtan and Coartem have unique and complex dosing regimens depending upon the patient's body weight for Coartem or the amount of levodopa/carbidopa for Comtan. As noted in the Coartem product information (page 2) the total regimen is 6 doses. However, depending on the patient's weight the Coartem dose may be 4 tablets twice daily, 2 tablets twice daily or 1 tablet twice daily. Similarly, the dose of Comtan can also be variable and is dependent upon the frequency of levodopa/carbidopa. These similar dosing frequencies increase the similarity of these two products.

Moreover, prescribers may write 'Take orally as directed' on the prescription and provide the detailed directions for the patient on a separate sheet of paper. This practice may circumvent the ability to initiate interventions by pharmacists and/or nurses when reviewing the prescription. If a patient were to receive Comtan instead of Coartem, there is the potential for ingestion of multiple tablets at once leading to

an adverse event secondary to drug toxicity. Conversely if Coartem were received instead of Comtan, there is the potential for inadequate treatment of Parkinson's disease.

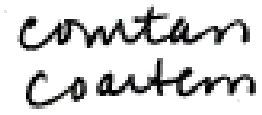
Based upon their look-alike characteristics when written and overlapping product characteristics such as dosage form (tablet), route of administration (oral) and frequency of administration (twice daily), the Division of Medication Error Prevention believes this name pair cannot safely coexist in the marketplace. Furthermore, 21 CFR 201.10(c)(5) states "the labeling of a drug may be misleading by reason (among other reasons) of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient."

III. COMMENTS TO THE SPONSOR

The findings of our Proprietary Name Risk Assessment indicate that the proposed name, Coartem, is vulnerable to name confusion that could lead to medication errors with Comtan. Our rationale is described in detail below. As such, the Division of Medication Error Prevention objects to the use of the proprietary name, Coartem for this product. We recommend you submit two alternate proprietary names and identify your primary and secondary choice.

Comtan and Coartem look similar when scripted and thus cannot be safely co-marketed.

Comtan and Coartem look similar when written because they share the first two letters ('Co') and end in letters that are not clearly distinguishable from each other ('an' vs. 'em'). Also, both of these names have an upstroke (lower case 't') in the same position of the names. This name pair also appears to be similar in length when written although Coartem is one letter longer.



Comtan and Coartem share some product characteristics such as the same route of administration (oral) and dosage form (tablet). They are also available in a single strength (120 mg/20 mg vs. 200 mg) which means prescriptions for either of these products could be prescribed and/or dispensed without an indication of strength. Additionally both Comtan and Coartem have unique and complex dosing regimens depending upon the patient's body weight for Coartem or the amount of levodopa/carbidopa for Comtan. As noted in the Coartem product information (page 2) the total regimen is 6 doses. However, depending on the patient's weight the Coartem dose may be 4 tablets twice daily, 2 tablets twice daily or 1 tablet twice daily. Similarly, the dose of Comtan can also be variable and is dependent upon the frequency of levodopa/carbidopa. These similar dosing frequencies increase the similarity of these two products.

Moreover, prescribers may write 'Take orally as directed' on the prescription and provide the detailed directions for the patient on a separate sheet of paper. This practice may circumvent the ability to recognize product differences by pharmacists and/or nurses when reviewing the prescription. If a patient were to receive Comtan instead of Coartem, there is the potential for

ingestion of multiple tablets at once leading to an adverse event secondary to drug toxicity. Conversely if Coartem were received instead of Comtan, there is the potential for inadequate treatment of Parkinson's disease.

Based upon the look-alike characteristics of this name pair when scripted and the overlapping product characteristics such as dosage form (tablet), route of administration (oral) and frequency of administration (twice daily), the Division of Medication Error Prevention believes this name pair cannot safely coexist in the marketplace. Furthermore, 21 CFR 201.10(c)(5) states "the labeling of a drug may be misleading by reason (among other reasons) of designation of a drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient."

Appears This Way On Original

Appendix A – Prescription Study Results for Coartem

Inpatient	Outpatient	Voice
Coartem	Cartem	Coarthum
Coartem	Cartera	Coartum
Coarlem	Coartern	Coartum
Coartem	Gartem	Coarthum
Coartem	Gartem	
Coartem	Gartem	
Coartem	Cartem	
Coartem	Cartesm	
	Gartem or	
Coartem	Coartem	
	Gartem	
	Gartera	
	Coartera	
	Gartem	
	Gartem	
	Cartesa	
	Gartem	

Appears This Way On Original

Appendix B. <u>Product characteristics and writing samples provided to medication error staff – poll</u>

Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
Coartem	Lumafantrine/artemether (COA5666) 120 mg/20 mg	<u>Treatment of malaria infection</u>: Adults and children weighing 35kg and above or older than 12 years of age: At diagnosis, the patient receives four tablets, then four tablets 8 hours later, and four tabs twice daily (morning and evening) on each of the following two days (total course =24 tablets)	
Comtan	Entacapone Tablet: 200 mg	<u>Adjunct treatment for Parkinson's Disease</u> 200 mg with each dose of levodopa/carbidopa, up to a maximum of 8 tablets/day	LA
Cotrim	Sulfamethoxazole 200 mg/5 mL, Trimethoprim 40 mg/5 mL Oral Suspension	<u>Chronic bronchitis, urinary tract infections, pneumocystis carinii pneumonia, shigellosis enteritis</u> 5 mL to 10 mL every 12 hours, every 6 hours or every 8 hours depending upon the diagnosis, severity of the infection and the weight of the patient.	LA

*Frequently used, not all-inclusive.
**LA (look-alike), SA (sound-alike)
*** Name pending approval. Not FOI releasable.

Writing Samples:

Is the name Comtan convincingly similar to Coartem such that practitioners would become confused at any point in the usual practice settings? Yes or no. Why or why not?
Is the name Cotrim convincingly similar to Coartem such that practitioners would become confused at any point in the usual practice settings? Yes or no. Why or why not.

If you believe the names are convincingly similar, could confusion between Comtan and Coartem conceivably result in medication errors in the usual practice setting? Yes or no. Why or why not.
If you believe the names are convincingly similar, could confusion between Cotrim and Coartem conceivably result in medication errors in the usual practice setting? Yes or No. Why or why not.

Appendix C. Orthographic and/or phonetic similarity between Comtan and the proposed name, Coartem – poll.

Poll question	Is the name Comtan convincingly similar to Coartem such that practitioners would become confused at any point in the usual practice setting?	Why or why not?
	yes	Strong look-alike, lack of directions (as directed)
	yes	If scripted poorly, the 'm' can look like 'ar' and 'tem' looks like 'tan'. They are both tablets, come in only one strength, and a prescription could be written without specifying the strength. They may also be placed in close proximity to each other in storage. Also the total daily dose for both products overlap at 8 tablets per day and could add to the confusion.
	yes	Have orthographic similarities
	yes	They have an identical beginning (Co-) and similar ending (-tan vs. –tem). The letters 'ar' can look similar to the letter 'm' when scripted; both have an upstroke 't' as the 3rd letter from the end of the name, which contributes to their similarity.
	yes	Both names resemble each other in script and are available in only one strength and it seems like the number of tablets ingested per day are similar
	yes	These names can appear almost identical.
	yes	The 'm' in Comtan and the 'ar' in Coartem look similar and the 'tan' and 'tem' also look similar.
	yes	Orthographic similarity self evident. No downstrokes, share 'Co-', 'm' looks like 'n' and upstrokes similarly located.
	yes	Numerous overlapping letters
	yes	Look similar when scripted

Appendix D. potential for confusion between Comtan and the proposed name, Coartem leading to medication errors - poll

Poll question	If you believe the names are convincingly similar, could confusion between Comtan and Coartem conceivably result in medication errors in the usual practice setting?	Why or why not?
	yes	Prescriber indicates 'as directed' (lp)
	Yes	Both avail as single strength, both have an achievable dose of 4 tablets, possibility of writing 'Use as directed' (fd)
	yes	Orthographic similarities and overlapping product characteristics (jj)
	yes	Both avail as single strength, written as 'use as directed', potentially overlapping dispense qty (ra)
	no	No overlapping strengths and different indications (km)
	yes	Single strength, overlap with total daily dose, 'as directed' (retail: many pts receiving coartem for travel to endemic areas) (kt)
	yes	Shared numerous overlapping letters (wf)
	no	Doses are different (zo)
	yes	Complex dosing instructions -> 'use as directed', single strength (therefore designation not necessary) (ja)
	yes	Orthographic similarity if scripted poorly, single strength, close proximity in pharmacy, total daily dose may overlap (lh)

Appendix E. Orthographic and/or phonetic similarity between Cotrim and the proposed name, Coartem – poll.

Poll question	Is the name Cotrim convincingly similar to Coartem such that practitioners would become confused at any point in the usual practice setting?	Why or why not?
	yes	Even though Cotrim is suspension, I could see pharmacist dispensing Bactrim as generic
	no	'Coar' looks longer than 'Co' and 'trim' looks longer than 'tem'. Also, product differences would prevent mix up.
	no	Coartem – 7 letters, Cotrim – 6 letters. The position of the 't' upstroke in Coartem is later in the word at the 5th letter compared to Cotrim at the 3rd letter.
	no	The upstroke 't' are in different locations (5th vs. 3rd position). The 'ar' in Coartem also lengthens the beginning of the name, adding more differentiation to the name.
	yes	Practitioners may just substitute cotrim with a tablet form, if they believed that coartem was cotrim. The frequency of administration is concerning since both are to be taken multiple times daily.
	no	The 'a' and 'r' between the 'o; and 't' in Coartem make it look much different.
	no	No overlapping dosage strengths and have very different indications
	yes	No downstrokes, share 'Co-', 'm' looks like 'n' and upstrokes similarly located
	yes	Numerous overlapping letters
	no	Coartem is longer and the placement of the cross stroke 't' differentiates these two names.

Appendix F. Potential for confusion between Cotrim and the proposed name, Coartem leading to medication errors – poll.

Poll Question	If you believe the names are convincingly similar, could confusion between Cotrim and Coartem conceivably result in medication errors in the usual practice setting?	Why or Why not?
	yes	Prescriber indicates 'as directed'
	No	't' in diff locations, '-ar' in Coartem lengthens and differentiates the name from Cotrim
	yes	Orthographic similarities and overlapping product characteristics
	no	No overlapping dosage strengths and different indications
	no	Dose would likely prevent mix-up
	yes	Share numerous overlapping letters
	no	Unconvincing orthographic similarity
	no	Unconvincing orthographic similarity
	no	Unconvincing orthographic similarity
	no	Unconvincing orthographic similarity, product differences

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/s/

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