

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204508Orig1s000

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
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review--Final

Date: September 6, 2013

Reviewer: Lisa V. Khosla, Pharm.D., M.H.A.
Division of Medication Error Prevention and Analysis

Team Leader: Lubna Merchant, MS, PharmD
Division of Medication Error Prevention and Analysis

Drug Name and Strength: Clinolipid (Lipid Injectable Emulsion, USP) 20%

Application Type/Number: NDA 204508

Applicant/sponsor: Baxter Healthcare Corporation

OSE RCM #: 2013-1763

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

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1 INTRODUCTION

This re-assessment of the proposed proprietary name, Clinolipid is written in response to the anticipated approval of this NDA within 90 days from the date of this review. DMEPA found the proposed name, Clinolipid, acceptable in OSE Review 2013-771 dated June 20, 2013.

2 METHODS AND DISCUSSION

For re-assessments of proposed proprietary names, DMEPA searches a standard set of databases and information sources (see section 4) to identify names with orthographic and phonetic similarity to the proposed name that have been approved since the previous OSE proprietary name review. For this review we used the same search criteria described in OSE Review 2013-771. We note that none of the proposed product characteristics were altered. However, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. The searches of the databases did not yield any new names thought to look or sound similar to Clinolipid and represent a potential source of drug name confusion.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The Safety Evaluator did not identify any United States Adopted Names (USAN) stems in the proposed proprietary name, as of September 5, 2013.

3 CONCLUSIONS

The re-evaluation of the proposed proprietary name, Clinolipid, did not identify any vulnerabilities that would result in medication errors with any additional names noted in this review. Thus, DMEPA has no objection to the proprietary name, Clinolipid, for this product at this time.

DMEPA considers this a final review; however, if approval of the NDA is delayed beyond 90 days from the date of this review, the Division of Gastroenterology and Inborn Error Products (DGIEP) should notify DMEPA because the proprietary name must be re-reviewed prior to the new approval date.

If you have further questions or need clarifications, please contact Phong Do, OSE project manager, at 301-796-4795.

4 REFERENCES

1. *Baugh, Denise V.; OSE Review 2013-771, Proprietary Name Review; June 20, 2013.*

2. *Drugs@FDA* (<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>)

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

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

USAN Stems List contains all the recognized USAN stems.

4. *Division of Medication Error Prevention and Analysis Proprietary Name Consultation Request*

Compiled list of proposed proprietary names submitted to the Division of Medication Error Prevention and Analysis for review. The list is generated on a weekly basis from the Access database/tracking system.

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

/s/

LISA V KHOSLA
09/06/2013

LUBNA A MERCHANT
09/06/2013

**Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management**

Proprietary Name Review

Date	June 20, 2013
Reviewer	Denise V. Baugh, PharmD, BCPS Division of Medication Error Prevention and Analysis
Team Leader	Lubna Merchant, PharmD, MS Division of Medication Error Prevention and Analysis
Division Director	Carol Holquist, R.Ph. Division of Medication Error Prevention and Analysis
Drug Name & Strength	Clinolipid (Lipid Injectable Emulsion, USP) 20%
Application Type/Number	NDA 204508
Applicant	Baxter Healthcare Corporation
OSE RCM #	2013-771

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Clinolipid, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

Clinolipid 20% has the same indication, route of administration, and dosing regimen as its Reference Listed Drug (RLD), Intralipid 20% Intravenous Fat Emulsion (NDA 018449) which was approved January 23, 1981. Intravenous Fat Emulsion is included in the list of drug shortages on the Agency's website. Therefore, this application is a priority review.

The previously proposed proprietary name, (b) (4) was found to be misleading.

(b) (4)

This preliminary finding was communicated to the Applicant March 7, 2013. As a result, the Applicant withdrew the name, (b) (4) and submitted the alternative proprietary name, Clinolipid, March 26, 2013.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 26, 2013 proprietary name submission.

- Active Ingredient: lipid injectable emulsion, USP, 20%
- Indication of Use: for parenteral nutrition providing a source of calories and essential fatty acids when oral or enteral nutrition is not possible, insufficient, or contraindicated
- Route of Administration: intravenous infusion
- Dosage Form: injectable emulsion
- Strength: 20%
- Dose and Frequency: dose depends upon energy expenditure, clinical status, body weight, tolerance, ability to metabolize and consideration of additional energy given to the patient; recommended dosing is as follows:

Population	Usual Daily Lipid dosage (g/kg/day)
Adults	1 to 1.5 (not to exceed 2.5)
(b) (4)	

- How Supplied: 1000 mL; 1000 mL/bag in a ‘6 pack’
- Storage: : 20°C to 25°C (68°F to 77°F)
- Container and Closure System: (b) (4) ported 1000 mL (b) (4) polyolefin bag. A (b) (4) clear overpouch (secondary packaging) provides protection from oxygen ingress and water loss during long term storage of the drug product

2. RESULTS

The following sections provide the information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP’s promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

The April 16, 2013 search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the prefix “Clin” is consistently used globally for their parenteral nutrition product line and it is also included in other FDA approved nutritional products that are marketed in the US such as “Clinimix” and “Clinisol”. The latter portion of the name “lipid” represents the drug product, a lipid emulsion.

Additionally, during the course of reviewing the name, we noted that the Applicant presented the name as “Clinolipid 20%”. DMEPA discourages the inclusion of percentages with proprietary names because it limits the options for the future addition of strengths to the product line. Furthermore, the percentage (when one is needed) traditionally follows the established name (active ingredient and dosage form). We

communicated this information to the Applicant by e-mail April 5, 2013. The Applicant submitted an amendment to the NDA to exclude the percentage from the proposed proprietary name on April 26, 2013.

2.2.3 FDA Name Simulation Studies

Forty-two practitioners participated in DMEPA’s prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. The most common trend was the misinterpretation of the letter string “-lip” for ‘bid’ or ‘pin’. We have considered these variations in our look-alike and sound-alike searches and analysis. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 5, 2013 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the proprietary name review.

2.2.5 Failure Mode and Effects Analysis of Similar Names

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Clinolipid. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Clinolipid identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, and Other Disciplines)					
Look Similar to CLINOLIPID					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Clonidine	FDA	Adapalene	Primary Reviewer	Clinacort	FDA
Clinac BPO	FDA	Alenaze-D	FDA	Aler-Dryl	FDA
Clevidipine	FDA	Clindagel	FDA	Clinisol	FDA
Clinoril	FDA	Clofibrate	FDA	(b) (4) ***	FDA
(b) (4) ***	FDA	Ipolipid	FDA	Clinimix	FDA
Glipizide	Primary Reviewer	Glucotrol	Primary Reviewer	Glimepiride	Primary Reviewer
Amiloride	Primary Reviewer	Clorazepate	Primary Reviewer	Clopidogrel	Primary Reviewer

Clinopodium	Primary Reviewer	Clomipramine	Primary Reviewer	Clomiphene	Primary Reviewer
Actalipid	FDA	Clonazepam	FDA		
Sound Similar to CLINOLIPID					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Klonopin	FDA				
Look and Sound Similar to CLINOLIPID					
<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>	<i>Name</i>	<i>Source</i>
Clinoleic ^{***}	FDA	Intralipid	FDA	Clinolipid	FDA

Our analysis of the thirty names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all thirty names will not pose a risk for confusion as described in Appendices D and E.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on May 9, 2013. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors Products (DGIEP) on May 9, 2013, they stated no additional concerns with the proposed proprietary name, Clinolipid.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Phong Do OSE Project Manager, at 301-796-4795.

3.1 COMMENTS TO THE APPLICANT

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

The proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA and the results are subject to change. If any of the proposed product characteristics as stated in your March 26, 2013 submission are altered, the name must be resubmitted for review.

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

4 REFERENCES

1. *Micromedex Integrated Index* (<http://csi.micromedex.com>)

Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. *Drug Facts and Comparisons, online version, St. Louis, MO*
(<http://factsandcomparisons.com>)

Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. *FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]*

DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

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

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

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

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

7. *U.S. Patent and Trademark Office* (<http://www.uspto.gov>)

USPTO provides information regarding patent and trademarks.

8. *Clinical Pharmacology Online* (www.clinicalpharmacology-ip.com)

Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common,

combination, nutraceutical and nutritional products. It also provides a keyword search engine.

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

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

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

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

11. Access Medicine (www.accessmedicine.com)

Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. USAN Stems (<http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml>)

USAN Stems List contains all the recognized USAN stems.

13. Red Book (www.thomsonhc.com/home/dispatch)

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

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

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

15. Medical Abbreviations (www.medilexicon.com)

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

16. CVS/Pharmacy (www.CVS.com)

This database contains commonly used over the counter products not usually identified in other databases.

17. Walgreens (www.walgreens.com)

This database contains commonly used over the counter products not usually identified in other databases.

18. Rx List (www.rxlist.com)

RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. Dogpile (www.dogpile.com)

Dogpile is a [Metasearch](#) engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. Natural Standard (<http://www.naturalstandard.com>)

Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, we consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.). DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.¹

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

¹ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/aboutMedErrors.html>. Last accessed 10/11/2007.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.²

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g., "T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 1 below for details).

² Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

Table 1. Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

Type of Similarity	Considerations when Searching the Databases		
	<i>Potential Causes of Drug Name Similarity</i>	<i>Attributes Examined to Identify Similar Drug Names</i>	<i>Potential Effects</i>
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication Names may look similar when scripted and lead to drug name confusion in written communication
	Orthographic similarity	Similar spelling Length of the name/Similar shape Upstrokes Down strokes Cross-strokes Dotted letters Ambiguity introduced by scripting letters Overlapping product characteristics	<ul style="list-style-type: none"> Names may look similar when scripted, and lead to drug name confusion in written communication
Sound-alike	Phonetic similarity	Identical prefix Identical infix Identical suffix Number of syllables Stresses Placement of vowel sounds Placement of consonant sounds Overlapping product characteristics	<ul style="list-style-type: none"> Names may sound similar when pronounced and lead to drug name confusion in verbal communication

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

safety of the proposed proprietary name or product based on professional experience with medication errors.

1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

2. Expert Panel Discussion

DMEPA gathers CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

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

3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

4. Comments from Other Review Disciplines

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

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.³ When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

³ Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

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

“Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?”

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

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

“Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?”

The answer to this question is a central component of the Safety Evaluator’s overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

- a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP’s findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].
- b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

- c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.
- d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.
- e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

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

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

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

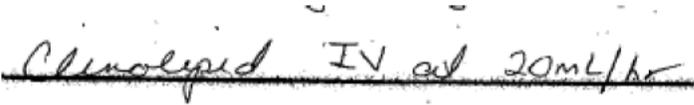
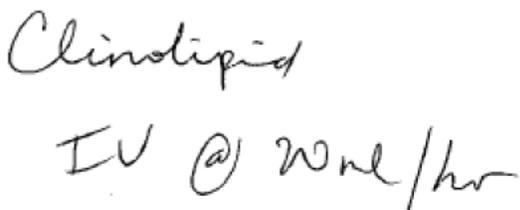
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency’s credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors’ have changed a product’s proprietary name in the post-approval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

Appendix B: Letters and Letter Strings with Possible Orthographic or Phonetic Misinterpretation

Letters in the Name	Scripted May Appear as	Spoken May Be Interpreted as
Clinolipid		
Capital 'C'	A, G, L, O, U	Z, K, S (if followed by an 'i' or 'e')
Lower case 'c'	a, e, i, l	z, k, s (if followed by an 'i' or 'e')
Lower case 'l'	b, e, s, A, P, i	
Lower case 'i'	l, e, o	e, a,
Lower case 'n'	m, u, ur x, r, h, s	dn, gn, kn, m, mn, pn
Lower case 'o'	a, c, e, u, d	Oh
Lower case 'p'	yn, ys, g, j, l, q	b
Lower case 'd'	cl, ci	b, t, n
Letter strings in the Name 'Clinolipid'	Scripted May Appear as	Spoken May Be Interpreted as
ol	d	-
Cl	D	Kl
Li	H	-
lip	liq, lig	lit, lik
id	od	ed
pid	Ped	bid
lipid	-	lipin

Appendix C: Prescription Simulation Samples and Results

Figure 1. Clinolipid Study (Conducted on April 5, 2013)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>“Clinolipid intravenously at the rate of 20 mL per hour”</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

INTERPRETATION	INPATIENT	VOICE	OUTPATIENT	TOTAL
CLINDIPID	0	0	2	2
CLINOLIBID	0	2	0	2
CLINOLIPID	10	6	7	23
CLINOLIPID IV	3	0	4	7
CLINOLIPIN	0	4	0	4
CLINOLOPID IV	0	0	1	1
CLINOMABID	0	1	0	1
CLINOPID	1	0	1	2

Appendix D: Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Proprietary Name	Active Ingredient	Similarity to Clinolipid	Failure preventions
1.	(b) (4)***	Fat Emulsion	Look Alike and Sound Alike	The proposed proprietary name, (b) (4)*** was found to be unacceptable by DMEPA due to the (b) (4) As a result of this communication with the Applicant, they proposed the alternative name, Clinolipid.
2.	Ipolipid	Gemfibrozil	Look Alike	The pair have sufficient orthographic and/or phonetic differences; Ipolipid is an international name for Gemfibrozil
3.	Actalipid	Atorvastatin	Look alike	The pair have sufficient orthographic and/or phonetic differences; Actalipid is an international name for Atorvastatin
4.	Clinolipid	Fat Emulsion	Look Alike and Sound Alike	Name is the subject of this review.
5.	Adapalene	Adapalene	Look alike	The pair have sufficient orthographic and/or phonetic differences
6.	Clomiphene	Clomiphene	Look alike	The pair have sufficient orthographic and/or phonetic differences
7.	Clomipramine	Clomipramine	Look alike	The pair have sufficient orthographic and/or phonetic differences
8.	Clinopodium (scientific)	Also known as basil thyme, baume sauvage,	Look Alike	Herbal product whose safety, effectiveness and dosage are

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

	name)	calament, calament de Montagne, Calaminta, Lesser Calamint, Mill Mint, Mountain balm, Mountain Mint, Pouliot de Montagne		unknown (Source: Natural Medicines Database); confusion with the name Clinolipid is not anticipated in the traditional medical setting
9.	(b) (4)***	Clonidine	Look-alike	DMEPA found the name (b) (4) unacceptable (OSE Review # 2008-487 dated June 20, 2008) because of the inclusion of the dosing frequency (BID) in the name which was found to be misleading. NDA 022331 was approved with the proprietary name, Kapvay in September, 2009. Therefore, confusion between the names (b) (4)*** and Clinolipid is not anticipated.
10.	(b) (4)***	Clonidine	Look alike	DMEPA found the name (b) (4) unacceptable (OSE Review# 2009-1526 dated November 10, 2009) due to its overlapping product characteristics with clonidine. However, it is not bioequivalent to Clonidine if given by the same dosing regimen and therefore was found to be a safety risk. NDA 022499 ws approved without a proprietary name December 3, 2009. Therefore, confusion between the names (b) (4)*** and Clinolipid is not anticipated
11.	Clofibrate	Active ingredient in Atromid-S	Look alike	The pair have sufficient orthographic and/or phonetic differences

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

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
1.	<p>Clevidipine (established name for Cleviprex) Injection emulsion for intravenous use</p> <p>25 mg/50 mL, 50 mg/100 mL</p> <p><i>Usual dose:</i></p> <p>Individualize dosage depending on the blood pressure response of the patient and the goal blood pressure; initial intravenous infusion rate is 1 to 2 mg/hour; most patients will achieve the desired response at approximately 4 to 6 mg/hour</p>	<p>Orthographic similarity is a result of sharing the same first two letters ('Cl') and having an up stroke ('d' vs. 'l') and a down stroke ('p') in the sixth and eighth positions, respectively within their names.</p> <p>Overlapping product characteristics include the dosage form (injectable emulsion) and the route of administration (intravenous).</p>	<p>The proposed name, Clinolipid includes an up stroke in the last position, which gives this name a different shape from that of Clevidipine.</p> <p>One differing product characteristic is the dose (1 mg/hour to 2 mg/hour vs. 1 gram/kg/day to 2.5 gram/kg/day).</p>

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
2.	<p>Clindagel (Clindamycin Phosphate) Topical Gel</p> <p>1%</p> <p><i>Usual dose:</i></p> <p>Apply a thin film once daily to the skin where acne lesions appear.</p>	<p>Orthographic similarity is a result of sharing the same first four letters ('Clin') and the fact that they have upstrokes and down strokes in similar positions within their names ('d' vs. 'l', 'g' vs. 'p' and 'd' vs. 'l').</p> <p>Both products have one strength and therefore, this information is not needed to dispense/administer the medication on a prescription.</p>	<p>The directions for Clindagel may be written as '<i>use as directed</i>', but a medication order for Clinolipid must include the rate of administration (e.g. mL/hour or mg/hour) and/or dose to be complete which will differentiate the Clinolipid order from Clindagel order</p>

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
3.	<p>Clinisol (Amino Acids) Injection 15% (ANDA 020512)</p> <p><i>Usual dose:</i> The total daily dose depends upon the daily protein requirements and on the patient's metabolic and clinical response; usual dose is 0.8 grams to 2 kg/kg/day depending upon the patient.</p>	<p>Orthographic similarity is a result of sharing the same first four letters ('Clin'). Additionally, both names end with an up stroke ('l' vs. 'd').</p> <p>Overlapping product characteristics include the dose (2 grams/kg/day), the route of administration (intravenous) and the duration of administration (continuous infusion). Additionally, Clinisol and Clinolipid would be used in the same patient populations and in similar healthcare settings.</p>	<p>The proposed name, Clinolipid, includes a down stroke ('p') in its name and a second up stroke ('l') which gives this name a different shape from Clinisol. Additionally, Clinolipid is longer in length when scripted.</p>

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
4.	Clinoril (Sulindac) Tablet 150 mg, 200 mg <i>Usual dose:</i> 150 mg to 200 mg orally twice daily (maximum: 400 mg per day)	Orthographic similarity is a result of sharing the same first four letters ('Clin'). Additionally, both names end with an up stroke ('l' vs. 'd'). Numerical similarity in strengths exists (200 mg vs. 20 gm)	The proposed name, Clinolipid, includes a down stroke ('p') in its name which gives this name a different shape from Clinoril. Additionally, Clinolipid is longer in length when scripted. Although numerical similarity in strengths exists between these two products,, the manner in which they are prescribed differs. For example, . the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Clinoril .

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
5.	Klonopin (Clonazepam) Tablet 0.5 mg, 1 mg, 2 mg <i>Usual dose:</i> 0.5 mg three times daily initially up to maximum daily dose of 20 mg	Orthographically, this name pair shares the same letters in the second, fourth, fifth, and seventh positions within their names ('l', 'n', 'o', and 'i'). Phonetic similarity stems from the similar sound of their first two letters ('Cl' vs. 'Kl') and the fact that these names share the same fourth and fifth letters ('no'). Additionally, their suffixes may sound similar when pronounced ('pin' vs. 'pid') as demonstrated in the voice simulation study. Numerical similarity in strengths exists (2 mg vs. 20 gm)	The proposed name, Clinolipid, includes two additional up strokes in the sixth and tenth positions ('l' and 'd') which gives this name a different shape from that of Klonopin. Although numerical similarity in strengths exists between these two products,, the manner in which they are prescribed differs. For example, . the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Klonopin.

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
6.	Intralipid (Fat Emulsion) Injection 20% <i>Usual dose:</i> 0.5 mL/minute for the first 15 to 30 minutes, then increase to 1 mL/minute if no adverse reactions occur. The daily dose should not exceed 2.5 grams of fat/kg of body weight (12.5 mL of Intralipid 20% per kg).	Orthographic similarity is a result of sharing the same suffix 'lipid' in the 6 th through 10 th positions. Additionally, their first two letters ('In' vs. 'Cl') may look similar in some handwriting samples. Overlapping product characteristics include strength (20%), the dose (2.5 grams/kg/day), the route of administration (intravenous) and the duration of administration (continuous infusion). Additionally, Intralipid and Clinolipid would be used in the same patient populations and in similar healthcare settings.	The letter string 'tra' (in Intralipid) does not look similar to the letter string 'ino' (in Clinolipid). when written..

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
7.	Aler-Dryl (Diphenhydramine) Tablet 50 mg <i>Usual dose:</i> 25 mg to 50 mg every 4 to 6 hours (not to exceed 300 mg per day)	Orthographic similarity stems from the similar appearance of their first four letters in some handwriting styles ('Aler' vs. 'Clin') and the fact that both names end with an up stroke ('l' vs. 'd'). There is the potential for a numerical overlap in dose (25 mg vs. 25 grams)	Although numerical similarity in doses exists between these two products,, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Aler-Dryl.
8.	Clinacort (Traiamcinolone Diacetate) Injection, Suspension 40 mg/mL <i>Usual dose:</i> 25 mg to 30 mg subcutaneously 1 to 2 times per week, 5 mg to 40 mg intra-articularly or intrasynovially every 1 to 8 weeks as needed, 3 mg to 48 mg intralesionally every 1 to 8 weeks as needed.	Orthographic similarity stems from sharing the same initial four letters ('Clin-') and the fact that both names end with an up stroke ('t' vs. 'd'). Both products have one strength and therefore, this information is not needed prior to dispensing/administering the medication. There is the potential for a numerical overlap in dose (25 mg vs. 25 grams)	The proposed name, Clinolipid includes an up stroke ('l') in the sixth position and one down stroke ('p') which gives this name a different shape from that of the marketed name, Clinacort. Although numerical similarity in doses exists between these two products,the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Clinacort.

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
9.	<p>Alenaze-D (Brompheniramine and Phenylephrine HCL) Solution 2 mg/5 mL and 7.5 mg/5 mL</p> <p>Alenaze-D NR (Brompheniramine and Phenylephrine HCL) Solution 4 mg/5 mL and 7.5 mg/5 mL</p> <p>Product is no longer marketed, but other products exist (in various concentrations)</p> <p><u>Usual dose:</u> 10 mL (4 mg of brompheniramine and 10 mg of phenylephrine respectively) every 4 hours</p>	<p>(Assessment assumes that the letter ‘z’ is written as a down stroke and that the modifier [‘D’ or ‘D NR’] is specified on a prescription and is presented in upper case letters).</p> <p>Orthographic similarity stems from the similar appearance of their first four letters in some handwriting styles (‘Alen’ vs. ‘Clin’) and the fact that they have a single down stroke (‘z’ and ‘p’) in their names.</p>	<p>The proposed name, Clinolipid, includes a second up stroke (‘l’) in its name which gives this name a different shape from that of Alenaze-D.</p> <p>The rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Alenaze-D</p> <p>Because there is more than one Alenaze product with a modifier, this information (‘D’ or ‘D NR’) would need to be included to dispense/administer the intended product.</p>

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
10.	<p>Clinac BPO (Benzoyl Peroxide) Gel 7%</p> <p><u>Usual dose:</u> Apply enough medication to cover the affected area and rub in gently once daily to up to 4 times daily.</p>	<p>Orthographic similarity stems from sharing the first four letters of their names ('Clin').</p> <p>Both products have one strength and therefore, this information is not needed prior to dispensing/administering the medication.</p> <p>Additionally, 'Clinac' (without the modifier) is not a marketed drug product, therefore, the modifier "BPO" is not required to dispense/administer the medication.</p>	<p>The proposed name, Clinolipid, includes two additional up strokes in the 6th and 10th positions ('l' and 'd') as well as a down stroke ('p') in the 8th position. This gives this name a different shape from that of the marketed name, Clinac. Additionally, the name, Clinolipid is longer in length when scripted.</p> <p>The directions for Clinac BPO may be written as '<i>use as directed</i>', but a medication order for Clinolipid must include the rate of administration (e.g. mL/hour or mg/hour) and/or dose to be complete which will differentiate the Clinolipid order from Clinac BPO order</p>

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
11.	<p>Clinimix (Amino Acids in Dextrose)</p> <p>2.75 %/10 gm/100 mL; 2.75 %/25 gm/100 mL; 2.75 %/5 gm/100 mL; 4.25 %/10 gm/100 mL; 4.25%/20 gm/100 mL; 4.25%/25 gm/100 mL; 4.25 %/5 gm/100 mL; 5 %/10 gm/100 mL, 5 %/15 gm/100 mL, 5 % 20 gm/100 mL, 5 %/25 gm/100 mL</p> <p><u>Usual dose:</u></p> <p>1 gram/kg to 1.5 grams/kg are usually sufficient to satisfy protein needs in adults</p>	<p>Orthographic similarity stems from sharing the first four letters of their names ('Clin').</p> <p>Overlapping product characteristics include the dose (1 gram/kg/day to 1.5 grams/kg/day), the route of administration (intravenous) and the duration of administration (continuous infusion). Additionally, Clinimix and Clinolipid would be used in the same patient populations and in similar healthcare settings.</p>	<p>The proposed proprietary name, Clinolipid, includes two additional up strokes ('l' and 'd') in the 6th and 10th positions and a down stroke ('p') in the 8th position. As a result, this name has a different shape from that of the marketed name, Clinimix.</p> <p>Clinimix is available in more than one strength and this information must be provided to dispense/administer the product as intended.</p>

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
12.	Clopidogrel (active ingredient in the drug product, Plavix) Tablet 75 mg, 300 mg <u>Usual dose:</u> 75 mg once daily (300 mg may be used as loading dose for non-ST myocardial infarction)	Orthographic similarity stems from sharing the first 2 letters ('Cl') of their names and both clopidogrel and Clinolipid include up strokes in similar positions within their names ('l' and 'd'). Numerical similarity between doses exists (300 mg vs. 30 gms).	The marketed name, clopidogrel, includes two down strokes ('p' and 'g') and one of them is in the fourth position. This differs from Clinolipid where there is a single down stroke in the 8 th position within the name. This difference gives these names different shapes. Although numerical similarity in doses exists between these two products,, the manner in which they are prescribed differs. For example, . the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Clopidogrel. Clopidogrel is available in more than one strength, this information must be included on a prescription to dispense/administer the medication as intended.
13.	Clorazepate (active ingredient in Tranxene-T) Tablet 3.75 mg, 7.5 mg, 15 mg <u>Usual dose:</u> 7.5 mg three times daily to 90 mg in divided doses	Orthographic similarity stems from sharing the first 2 letters ('Cl') of their names and having a single down stroke ('p'). The potential for numerical similarity between doses exists (7.5 mg vs. 75 gm).	The proposed name, Clinolipid includes two additional up strokes ('l' and 'd') vs. one cross stroke ('t') in the marketed name, clorazepate. Thus, these names have different shapes. Although numerical similarity in doses exists between these two products,, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Clorazepate.. Clorazepate is available in more than one strength and this information must be provided to dispense/administer the product as intended

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
14.	Amiloride (active ingredient in the drug product, Midamor) Tablet 5 mg <u>Usual dose:</u> 5 mg once daily	Orthographic similarity stems from the similar appearance of the letter 'A' (in Amiloride) and the letters 'CI' (in Clinolipid) in some handwriting samples. Both products have one strength and therefore, this information is not needed prior to dispensing/administering the medication.	The proposed name, Clinolipid includes two additional up strokes in the 6 th and 10 th positions whereas these same up strokes appear in the 4 th and 8 th positions in the marketed name, Amiloride. Additionally, Clinolipid has a single down stroke ('p') within its name which gives it a different shape from Amiloride. The rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Amiloride.
15.	Glimepiride (active ingredient in the drug product, Amaryl) Tablet 1 mg, 2 mg, 4 mg <u>Usual dose:</u> 1 mg to 2 mg once daily up to a maximum of 8 mg once daily	Orthographic similarity stems from the similar appearance of their first four letters ('Glim' vs. 'Clin') in some handwriting samples and the fact that they share a single down stroke ('p') within their names. The potential for numerical similarity in dose exists (4 mg vs. 40 gm)	The proposed name, Clinolipid has two additional up strokes ('l' and 'd') in contrast to Glimepiride which has one additional up stroke ('d'). This gives these names different shapes when scripted. Although numerical similarity in doses exists between these two products, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Glimepiride.. Glimepiride is available in more than one strength and this information must be provided to dispense/administer the product as intended

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
16.	Glucotrol (Glipizide) Tablet 5 mg, 10 mg <u>Usual dose:</u> 5 mg once daily up to a maximum of 20 mg once daily	Orthographic similarity stems from the similar appearance of their first 2 letters ('Gl' vs. 'Cl') in some handwriting samples and the fact that both names have an up stroke ('l' vs. 'd') at the end of their names. There is the potential for numerical similarity in dose (20 mg vs. 20 gm).	The proposed name, Clinolipid, includes a single down stroke ('p') in its name while one of the letters in Glucotrol is a cross stroke ('t'). These differences give these names different shapes. Although numerical similarity in doses exists between these two products, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Glucotrol. Glucotrol is available in more than one strength and this information must be provided to dispense/administer the product as intended
17.	Glipizide (active ingredient in Glucotrol) 5 mg, 10 mg <u>Usual dose:</u> 5 mg once daily up to a maximum of 20 mg once daily	Orthographic similarity stems from the similar appearance of their first 2 letters ('Gl' vs. 'Cl') in some handwriting samples and the fact that both names have a single down stroke ('p') in their names. The potential for numerical similarity in dose exists (20 mg vs. 20 gm)	The proposed name, Clinolipid, includes one additional up stroke in the 6 th position within its name and the letter 'd' appears at the end of its name. Therefore, this name has a different shape from the marketed name, Glipizide. Although numerical similarity in doses exists between these two products,, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Glipizide. Glipizide is available in more than one strength and this information must be provided to dispense/administer the product as intended

No.	Proposed name: Clinolipid Dosage Form(s): Injectable emulsion, USP Strength(s): 20% (20 grams/100 mL) Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)	Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion Causes (could be multiple)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
18.	<p>Clonidine</p> <p>Tablets: 0.1 mg, 0.2 mg, 0.3 mg</p> <p>Usual dose for tablets: 0.2 mg to 0.6 mg given in divided doses (up to 2.4 mg)</p> <p>Transdermal: 0.1 mg/24 hr, 0.2 mg/24 hr, 0.3 mg/24 hr</p> <p>Usual dose for Transdermal System: 0.1 mg/24 hr to 0.3 mg/24 hr every 7 days</p> <p>Injection: 100 mcg/mL, 500 mcg/mL</p> <p>Usual dose for Injection: 30 mcg/hour to 40 mcg/hour as continuous epidural infusion</p>	<p>Orthographic similarity stems from sharing the same first 2 letters ('Cl').</p> <p>One overlapping product characteristic for the parenteral forms of Clonidine and Clinolipid is that both products are given by continuous infusion and their rates of administration are "XX per hour" (e.g., mcg/hour or mL/hour).</p>	<p>The proposed name, Clinolipid includes a single down stroke ('p') and two up strokes ('l' an 'd') which gives this name a different shape. Additionally, although both names include the letter 'd', this letter appears at the end of the name Clinolipid in contrast to Clonidine where it appears in the 4th location from the last position in Clonidine.</p> <p>Since Clonidine is available in different strengths and dosage forms and is given by different routes of administration, all of this information must be included to dispense/administer the medication as intended.</p>

No.	<p>Proposed name: Clinolipid</p> <p>Dosage Form(s): Injectable emulsion, USP</p> <p>Strength(s): 20% (20 grams/100 mL)</p> <p>Usual Dose: 1 gram to 1.5 grams/kg/day (not to exceed 2.5 grams/kg/day)</p>	<p>Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion</p> <p>Causes (could be multiple)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
19.	<p>Clonazepam (the active ingredient in the marketed product, Klonopin) Tablet</p> <p>0.5 mg, 1 mg, 2 mg</p> <p><i>Usual dose:</i></p> <p>0.5 mg three times daily initially up to maximum daily dose of 20 mg</p>	<p>Orthographically similarity stems from sharing the same letters in the first, second, fourth, and eight positions ('C', 'l', 'n' and 'p').</p> <p>The potential for numerical similarity exists (20 mg vs. 20 gm).</p>	<p>The proposed name, Clinolipid, includes two additional up strokes in the sixth and tenth positions ('l' and 'd') which gives this name a different shape from that of Clonazepam.</p> <p>Although numerical similarity in doses exists between these two products, the manner in which they are prescribed differs. For example, the rate of administration (e.g. mL/hour or mg/hour) for Clinolipid must be included in the medication order to be compounded and administered as intended. This will differentiate the Clinolipid order from that of Clonazepam.</p> <p>Since Clonazepam is available in more than one strength, this information must be provided prior to dispensing/administering the medication.</p>

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/s/

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