

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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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 Medication Error Prevention and Risk Management**

Proprietary Name Review

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Drug Name and Strength: Sklice (Ivermectin) Topical Lotion 0.5%

Applicant/sponsor: Topaz Pharmaceuticals.

OSE RCM #: 2011-3183

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

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Sklice, 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. The proposed product characteristics are provided in section 1.2 below.

1.1 REGULATORY HISTORY

This review responds to a request from Topaz Pharmaceuticals, dated August 23, 2011, for a safety and promotional assessment of the proposed proprietary name, Sklice (NDA 202736). The name was previously reviewed by DMEPA in the original submission of a request for proprietary name, to IND 073134 on March 18, 2010, and was found acceptable in OSE review #2010-664, dated September 15, 2010. However, in that review, DMEPA advised the Applicant that if in their future development program for this product, the Applicant decides to expand the indication of use, DMEPA would find the proposed name 'Sklice' misleading because the name 'Sklice' implies that the product treats only lice.

Additionally, the Applicant submitted container label, carton labeling, and Prescribing Information on August 24, 2011 which will be reviewed under a separate cover in OSE review #2011-3115

1.2 PRODUCT CHARACTERISTICS

Sklice (Ivermectin) Topical Lotion 0.5% is an (b) (4) indicated for the topical treatment of head lice (b) (4) in patients 6 months of age and older. Sklice is applied to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp, and rinsed off with water after 10 minutes.

Sklice is supplied in a four ounce laminate tube and can be stored at room temperature.

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

OPDP determined that the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Dermatology and Dermal Products (DDDP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following information is considered in the safety assessment of the proposed name.

2.2.1 *United States Adopted Names (USAN) SEARCH*

The United States Adopted Name (USAN) stem search conducted on September 1, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 *Components of the Proposed Proprietary Name*

The proposed proprietary name is comprised of one word. The one word contains the letter string '-lice' in the name which reflects the indication for this product (i.e. for the treatment of lice). DMEPA does not support the use of the indication as part of the proprietary name because the name may not support any additional indications that come from future development. Although, the letter string '-lice' is acceptable for this product, if future development leads to a new

indication, the name Sklice may not be appropriate if the indications are significantly different from lice as determined by DMEPA.

2.2.3 External Proprietary Name Risk Assessment

An external name risk assessment conducted by (b) (4) and submitted by the Applicant in the Request for Proprietary Name Review on August 23, 2011, identified no concerns on the suitability of the name, Sklice.

2.2.4 FDA Name Simulation Studies

Twenty-four practitioners responded to DMEPA’s prescription studies. None of the responses overlapped with other drug names that are currently marketed. Twelve participants interpreted the proposed proprietary name correctly as ‘Sklice’ with four correct interpretations (n=4) occurring with inpatient orders, two correct interpretations (n=2) occurring with outpatient orders, and six correct interpretations (n=6) occurring with the voice orders. One additional practitioner identified the correct spelling of Sklice, but responded by presenting the first two letters ‘Sk’ as a modifier in the beginning of the name (i.e. Sk Lice). One participant (n=1) misinterpreted the letter ‘k’ as ‘p’, and four participants (n=4) misinterpreted the letter ‘k’ as the letter ‘r’, with the inpatient order. One participant (n=1) misinterpreted the letter ‘S’ as the letter ‘A’ with the outpatient order. See Appendix C for sample prescriptions used in the study and the complete listing of interpretations from the verbal and written prescriptions studies.

2.2.5 Comments From Other Review Disciplines

In response to OSE e-mail, dated September 1, 2011, the Division of Dermatology and Dental Products (DMEP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

2.2.6. Failure Mode and Effects Analysis of Similar Names

Table 1 lists the names identified to have potential orthographic, phonetic, or spelling similarity to the proposed proprietary name, Sklice (see Appendix B). These names were identified by the primary reviewer, the Expert Panel Discussion (EPD), and other review disciplines. Table 1 also includes the names identified by (b) (4) that were not previously identified by DMEPA and require further evaluation.

Table 1: Collective List of Potentially Similar Names (DMEPA, EPD and Other Disciplines)

Look Similar		Look and Sound Similar	
Name	Source	Name	Source
Skelaxin	EPD Panel	Sprix	EPD Panel
Skelid	EPD Panel	Spycel	EPD Panel
Altace	EPD Panel	(b) (4)	Safety

			Evaluator
(b) (4)	EPD Panel		
Look Similar		Look and Sound Similar	
<i>Name</i>	<i>Source</i>		
Gralise	EPD Panel		
Clistin	EPD Panel		
Acilac	EPD Panel		
Silace	EPD Panel		
Starlix	EPD Panel		
SSKI	EPD Panel		
Solage	EPD Panel		
Acticin	Safety Evaluator		
Alinia	Safety Evaluator		
Alli	Safety Evaluator		
Aloxi	Safety Evaluator		
Glyset	Safety Evaluator		
Tice	Safety Evaluator		
(b) (4)	Safety Evaluator		
Stelara	Safety Evaluator		
NoLice Hair Treatment	(b) (4)		
Saline			
Silvadene			
Salex			

Our analysis of the 26 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined all 26 names will not pose a risk for confusion as described in Appendices D and E.

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DMEPA communicated these findings to the Division of Dermatology and Dental Products via e-mail on October 14, 2011. At that time we requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Dermatology and Dental Products on October 26, 2011 the Division had no additional concerns with the proposed proprietary name, Sklice.

3 CONCLUSIONS

DMEPA concludes the proposed proprietary name, Sklice is acceptable from both a promotional and safety perspective. However, if any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

The proposed proprietary name, Sklice, must be re-reviewed if NDA approval is delayed beyond 90 days.

Please copy the Division of Medication Error Prevention and Analysis on any communication to the Applicant with regard to this review. If you have further questions or need clarifications on this review, please contact the OSE Regulatory Project Manager, Janet Anderson, project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

We have concluded our review of the proposed proprietary name, Sklice, and have concluded that it is acceptable from both a promotional and safety perspective.

However, if your future development program includes expansion of the indication of use of this product, we may find the proposed name 'Sklice' misleading for other indications if it is determined by DMEPA that the new indication is significantly different from treatment of Lice.

If any of the proposed product characteristics as stated in this review are altered, DMEPA rescinds this finding and the name must be resubmitted for review. The conclusions upon re-review are subject to change.

The proposed proprietary name, Sklice, must be re-reviewed if NDA approval is delayed beyond 90 days.

4 REFERENCES

OSE Review #2010-664, Sklice (Ivermectin) Cream Proprietary Name Review, Miller, C., September 15, 2010.

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

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

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

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

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

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

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

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

8. ***U.S. Patent and Trademark Office*** (<http://www.uspto.gov>)
USPTO provides information regarding patent and trademarks.
9. ***Clinical Pharmacology Online*** (www.clinicalpharmacology-ip.com)
Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.
10. ***Data provided by Thomson & Thomson's SAEGIS™ Online Service, available at*** (www.thomson-thomson.com)
The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.
11. ***Natural Medicines Comprehensive Databases*** (www.naturaldatabase.com)
Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.
12. ***Access Medicine Database*** (<http://www.accessmedicine.com/drugs.aspx>)
Access Medicine contains full-text information from approximately 60 medical titles: it includes tables and references. Among the database titles are: Goodman and Gilman's The Pharmacological Basis of Therapeutics, Current Medical Diagnosis and Treatment, Tintinalli's Emergency Medicine, and Hurst's the Heart.
13. ***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.
14. ***Red Book Pharmacy's Fundamental Reference***
Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.
15. ***Lexi-Comp*** (www.lexi.com)
Lexi-Comp is a web-based searchable version of the Drug Information Handbook.
16. ***Medical Abbreviations Book***
Medical Abbreviations Book contains commonly used medical abbreviations and their definitions.
17. ***LabelDataPlus Database*** (<http://www.labeldataplus.com/index.php?ns=1>)
LabelDataPlus database covers a total of 36773 drug labels. This includes Human prescription drug labels as well as Active Pharmaceutical Ingredients (APIs), OTC

(Application and Monograph) drugs, Homeopathic drugs, Unapproved drugs, and Veterinary drugs.

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

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. 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 product characteristics considered for this review appears in Appendix B1 of this review.

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 Division of Drug Marketing, Advertising, and Communications (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 Appendix B1 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

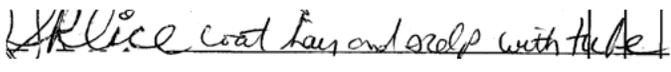
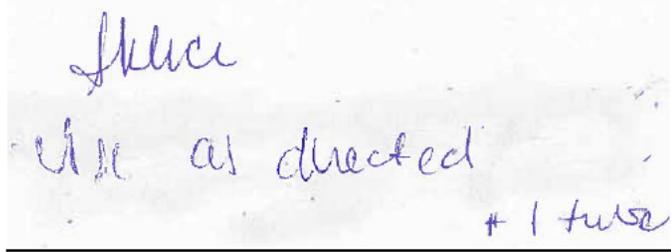
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval 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 with Possible Orthographic or Phonetic Misinterpretation

Letters in Name, Sklice	Scripted May Appear as	Spoken May Be Interpreted as
Capital letter 'S'	'G', '5', 'L', 'O', 'A'	'X'
Lower case 's'	'G', '5', 'g', 'n'	'x'
Lower case 'k'	'x', 'h', 'la', 'b', 'R'	'c', 'g'
Lower case 'l'	'b', 'e', 's', 'A', 'P', 'i', 't'	
Lower case 'i'	'e', 'l', 'j', 't'	'a', 'e'
Lower case 'c'	'a', 'e', 'i', 'l'	'z', 'k', 's' if followed by an 'e' or 'i'
Lower case 'e'	'a', 'i', 'l', 'o', 'u', 'p'	Any vowel

Appendix C: Prescription Simulation Samples and Results

Figure 1. Sklice Study (9/2/2011)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Sklice Use as directed # 1 tube</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (n=24)

Inpatient Medication Order	Outpatient Prescription	Voice Prescription
SK Lice	Aklice	Sclice
Sklice	Sklece	Sclise
Sklice	Sklice	Sclyce
Sklice	Sklice	Sclys
Sklice		Sklice
Splice		Sklice
Sr Lice		Sklice
Srlice		Sklice
Srlice		Sklice
Srlice		Sklice

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

Product Name	Similarity to Sklice	Failure preventions
(b) (4)		
NoLice Hair Treatment	(b) (4)	The name lacks convincing orthographic or phonetic similarity to Sklice.
Spycel	Sound alike	The name lacks convincing orthographic or phonetic similarity to Sklice.
Solage	Look alike	Product is discontinued with no generic equivalents available.

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

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.

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Skelaxin (Metaxalone) Tablets, 800 mg</p> <p><u>Usual Dose</u> One tablet by mouth 3 or 4 times daily.</p>	<p><u>Orthographic</u> Both names start with the letter string 'Sk-' and contain the upstroke 'l' placed in a similar position in the name (third position in Sklice vs. the fourth in Skelaxin).</p> <p><u>Strength</u> Single strength</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one tablet</p>	<p><u>Orthographic</u> The name Skelaxin appears longer than Sklice when scripted due to the extra letters 'i' and 'n' in Skelaxin. Additionally, the cross stroke 'x' in Skelaxin may help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets</p> <p><u>Frequency of Administration</u> One application vs. 3 or 4 times daily</p>

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Skelid (Tiludronate Sodium) Tablets, 200 mg</p> <p><u>Usual Dose</u> 400 mg (2 tablets) by mouth daily for a period of 3 months.</p>	<p><u>Orthographic</u> Both names consist of 6 letters and begin with the letter string 'Sk-'. Additionally, the letter string '-li-' in Sklice may appear similar to the letter string '-el-' in Skelid when scripted.</p> <p><u>Strength</u> Single strength</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. four upstrokes ('S', 'k', 'l', and 'd') in Skelid.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets</p> <p><u>Frequency of Administration</u> One application vs. once daily for 3 months.</p> <p><u>Usual Dose</u> Apply up to 1 tube (4 ounces) or 'as directed' vs. 400 mg (or 2 tablets).</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Altace (Ramipril) Capsules 1.25 mg, 2.5 mg, 5 mg, 10 mg</p> <p><u>Usual Dose</u> 1.25 mg to 10 mg by mouth once daily</p>	<p><u>Orthographic</u> Both names consist of 6 letters and end with the letter string '-ce'. Additionally, the letter string 'Skli-' in Sklice may appear similar to the letter string 'Alta-' in Altace when scripted.</p> <p><u>Partial Numerical Overlap in the Strength</u> 0.5% vs. 5 mg</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one capsule</p>	<p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. capsules</p> <p><u>Frequency of Administration</u> One application vs. once daily</p>
<p>Gralise (Gabapentin) Extended-release Tablets 300 mg, 600 mg</p> <p><u>Usual Dose</u> Initially, 300 mg by mouth 3 times daily, may increase to 600 mg 3 times daily.</p>	<p><u>Orthographic</u> The letter string '-lice' and the letter 'S' in Sklice may appear similar to the letter string '-lise' and the letter 'G' in Gralise when scripted.</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one tablet</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. two upstrokes ('G', 'l') in Gralise.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets</p> <p><u>Strength</u> 0.5% vs. 300 mg and 600 mg</p> <p><u>Frequency of Administration</u> One application vs. 3 times daily</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Clistin (Carbinoxamine) Tablets or solution 4 mg or 4 mg/5 mL</p> <p>(Discontinued, but available under the name Palgic)</p> <p><u>Usual Dose</u> One to two tablets by mouth or 5 to 10 mL by mouth 3 to 4 times daily.</p>	<p><u>Orthographic</u> Both names consist of 3 upstrokes ('S', 'k', 'l' in Sklice and 'C', 'l', 't' in Clistin). Additionally, the letter string '-kl-' in Sklice may appear similar to the letter string '-li-' in Clistin when scripted.</p> <p><u>Strength</u> Single strength</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> 4 ounces vs. 4 mg</p>	<p><u>Orthographic</u> The location of cross stroke 't' (fifth position) in Clistin may help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets or oral solution</p> <p><u>Frequency of Administration</u> One application vs. 3 to 4 times daily.</p>
<p>Acilac (Lactulose) Oral solution 10 g/15 mL</p> <p><u>Usual Dose</u> Adults: 30 to 45 mL by mouth 3 to 4 times daily. Children: 40 to 90 mL/day given in 3 to 4 divided doses.</p>	<p><u>Orthographic</u> Both names consist of 6 letters. Additionally, the letter 'S' and the letter string '-lic-' in Sklice may appear similar to the letter 'A' and the letter string '-lac' in Acilac when scripted.</p> <p><u>Strength</u> Single strength</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. two upstrokes ('A', 'l') in Acilac.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. oral solution</p> <p><u>Frequency of Administration</u> One application vs. 3 to 4 times daily</p> <p><u>Usual Dose</u> Apply one tube (4 ounces) or 'as directed' vs. 30 to 45 mL.</p>

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Silace (Docusate Sodium) Oral syrup or liquid 20 mg/5 mL or 10 mg/mL</p> <p><u>Usual Dose</u> Adults: 15 mL to 90 mL by mouth daily (syrup) or 5 mL to 20 mL daily (liquid). Pediatrics: 15 to 37.5 mL by mouth daily (syrup) or 2 mL to 12 mL daily (liquid).</p>	<p><u>Orthographic</u> Both names consist of 6 letters and start with the letter 'S'. Additionally, the letter string '-lice' in Sklice may appear similar to the letter string '-lace' in Silace when scripted.</p> <p><u>Possible Numerical Overlap in the Usual Dose</u> 4 ounces vs. 4 mL</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. two upstrokes ('S', 'l') in Silace.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. oral syrup (or liquid)</p> <p><u>Strength</u> 0.5% vs. 20 mg/5 mL or 10 mg/mL</p> <p><u>Frequency of Administration</u> One application vs. daily</p>

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Starlix (Nateglinide) Tablets 60 mg, 120 mg</p> <p><u>Usual Dose</u> 60 mg to 120 mg 3 times daily 1 to 30 minutes prior to meals.</p>	<p><u>Orthographic</u> The letter string 'Sk-' in Sklice may appear similar to the letter string 'St-' in Starlix when scripted. Additionally, both names contain the letter string '-li-'.</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one tablet</p>	<p><u>Orthographic</u> The upstroke 'x' in Starlix and the position of the upstroke 'l' in the two names (third position in Sklice vs. the 5th position in Starlix) can help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets</p> <p><u>Strength</u> 0.5% vs. 60 mg and 120 mg</p> <p><u>Frequency of Administration</u> One application vs. 3 times daily.</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
SSKI (Potassium Iodide) Oral Solution 1 gram/mL <u>Usual Dose</u> 300 mg (0.3 mL) to 600 mg (0.6 mL) 3 times daily.	<u>Orthographic</u> Both names start with the letter ‘S’. Additionally, the letter string ‘-kl-’ in Sklice may appear similar to the letter string ‘-ki-’ in SSKI when scripted. <u>Strength</u> Single strength	<u>Orthographic</u> The name Sklice appears longer than SSKI when scripted due to the extra letters ‘c’ and ‘e’ in Sklice. <u>Route of Administration</u> Topical vs. oral <u>Dosage Form</u> Lotion vs. oral solution <u>Frequency of Administration</u> One application vs. 3 times daily <u>Usual Dose</u> Apply up to one tube (4 ounces) or ‘as directed’ vs. 300 to 600 mg (or 0.3 to 0.6 mL).
Stelara (Ustekinumab) Injection 45 mg/0.5 mL, 90 mg/mL <u>Usual Dose</u> 45 mg to 90 mg initial dose; then four weeks later; followed by every twelve weeks via subcutaneous injection.	<u>Orthographic</u> The name Sklice may appear similar to the letter string ‘Stelar-’ when scripted. <u>Overlap in the Frequency of Administration</u> Once or times one <u>Partial Numerical Overlap in the Strength</u> 0.5% in Sklice vs. 0.5 mL in Stelara.	<u>Route of Administration</u> Topical vs. subcutaneous <u>Dosage Form</u> Lotion vs. injection <u>Usual Dose</u> Apply up to one tube (4 ounces) or ‘as directed’ vs. 45 to 90 mg

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Sprix (Ketorolac Tromethamine) Nasal spray 15.75 mg/100 uL</p> <p><u>Usual Dose</u> 1.5 mg (15.75 mg) spray into each nostril every 6 to 8 hours. Maximum daily dose is 126 mg (four doses).</p>	<p><u>Orthographic/Phonetic</u> Both names start with the letter ‘S’ and contain the letter ‘i’ in the 4th position. Phonetically, both names consist of two syllables and share the same first syllable (‘S-’).</p> <p><u>Strength</u> Single strength</p> <p><u>Possible Overlap in the Usual Dose</u> As directed</p>	<p><u>Orthographic/Phonetic</u> 3 upstrokes (‘S’, ‘k’, ‘l’), no downstrokes, and no cross strokes in Sklice vs. one upstroke (‘S’), one downstroke (‘p’), and one cross stroke (‘x’) in Sprix. Phonetically, the second syllable of each name (‘-klice’ vs. ‘-prix’) can help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. intranasal</p> <p><u>Dosage Form</u> Lotion vs. nasal spray</p> <p><u>Frequency of Administration</u> One application vs. every 6 to 8 hours</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode

(b) (4)

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Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Glyset (Migitol) Tablets 25 mg, 50 mg, 100 mg</p> <p><u>Usual Dose</u> 25 mg to 100 mg by mouth 3 times daily.</p>	<p><u>Orthographic</u> Both names consist of 6 letters. Additionally, the letter strings ‘Sk-‘ and ‘-ce’ in Sklice may appear similar to the letter strings ‘Gl-‘ and ‘-se-‘ in Glyset when scripted.</p> <p><u>Numerical Overlap in the Strength</u> 0.5% vs. 50 mg</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one tablet</p>	<p><u>Orthographic</u> One downstroke ‘y’ in Glyset vs. none in Sklice. Additionally, the cross stroke ‘t’ at the end of the name Glyset may help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. oral</p> <p><u>Dosage Form</u> Lotion vs. tablets</p> <p><u>Frequency of Administration</u> One application vs. 3 times daily.</p>

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Tice (Bacillus of Calmette and Guerin BCG Live) Injection, 0.5%</p> <p><u>Usual Dose</u> Instilled into bladder after reconstitution via catheter; retained for two hours then voided.</p>	<p><u>Orthographic/Phonetic</u> Both names share the letter string '-ice'. Phonetically, both names share the 'ice' sound.</p> <p><u>Strength</u> Single strength</p>	<p><u>Orthographic/Phonetic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. one upstroke ('T') in Tice. Additionally, the name Sklice appears longer than the name Tice when scripted because of the extra letters 'S' and 'k' in Sklice. Phonetically, there are two syllables in Sklice ('s', '-klice') vs one syllable ('tice') in Tice. Additionally, the 'T' vs. 'S' and the 'kl' sounds provides phonetic variation when pronounced.</p> <p><u>Route of Administration</u> Topical vs. intrabladder</p> <p><u>Dosage Form</u> Lotion vs. injection</p> <p><u>Usual Dose</u> Apply up to one tube (4 ounces) or 'as directed' vs. instill contents into bladder.</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
Alinia (nitazoxanide) Tablets or oral suspension 500 mg or 100 mg/5 mL <u>Usual Dose</u> One tablet or 5 mL, 20 mL, or 25 mL every twelve hours for 3 days.	<u>Orthographic</u> Both names consist of 6 letters. Additionally, the letter strings ‘Skli-‘ and ‘-ice’ in Sklice may appear similar to the letter strings ‘Ali-‘ and ‘-nia’ in Alinia when scripted. <u>Strength</u> Single strength <u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one tablet	<u>Orthographic</u> 3 upstrokes (‘S’, ‘k’, ‘l’) in Sklice vs. two upstrokes (‘A’, ‘l’) in Alinia. <u>Route of Administration</u> Topical vs. oral <u>Dosage Form</u> Lotion vs. tablets or oral suspension <u>Frequency of Administration</u> One application vs. every 12 hours for 3 days.
Alli (Orlistat) Capsules 60 mg <u>Usual Dose</u> One capsule with each meal containing fat.	<u>Orthographic</u> The letter string ‘Skli-‘ in Sklice may appear similar to the name Alli when scripted. <u>Strength</u> Single strength <u>Possible Overlap in the Frequency of Administration</u> Once or ‘times one’ <u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one capsule	<u>Orthographic</u> The name Sklice appears longer than the name Alli when scripted due to the extra letters ‘c’ and ‘e’ in Sklice. <u>Route of Administration</u> Topical vs. oral <u>Dosage Form</u> Lotion vs. capsules

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Aloxi (Paionosetron Hydrochloride) Capsules or injection 0.5 mg or 0.25 mg/5 mL</p> <p><u>Usual Dose</u> One 0.5 mg capsule one hour before chemotherapy, or 0.25 mg injection intravenously over thirty minutes before starting chemotherapy.</p>	<p><u>Orthographic</u> The letter string 'Sk-' in Sklice may appear similar to the letter string 'Al-' in Aloxi when scripted.</p> <p><u>Strength</u> Single strength</p> <p><u>Possible Overlap in the Frequency of Administration</u> Once or 'times one'</p> <p><u>Partial Numerical Overlap in the Usual Dose</u> One tube vs. one capsule</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. two upstrokes ('A', 'l') in Aloxi. Additionally, the cross stroke 'x' Aloxi may help differentiate the two names.</p> <p><u>Route of Administration</u> Topical vs. oral or intravenous</p> <p><u>Dosage Form</u> Lotion vs. capsules or injection</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Acticin (Permethrin) Cream 5%</p> <p><u>Usual Dose</u> Massage into skin from head to feet. Usually 30 grams. Remove by washing after six to fourteen hours. One application.</p>	<p><u>Orthographic</u> The letter string '-lice' in Sklice may appear similar to the letter string '-tici-' in Acticin when scripted. Additionally, the letter 'S' in Sklice may also appear similar to the letter 'A' in Acticin.</p> <p><u>Overlap in the Route of Administration</u> Topical</p> <p><u>Overlap in the Dosage Form</u> Topical dosage form</p> <p><u>Strength</u> Single strength and numerical overlap in strength (0.5% vs. 5%)</p> <p><u>Overlap in the Frequency of Administration</u> One time</p> <p><u>Usual Dose</u> Use as directed</p>	<p><u>Orthographic</u> 3 upstrokes ('S', 'k', 'l') in Sklice vs. two upstrokes ('A', 't') in Acticin. The name Acticin appears longer than Sklice when scripted due to the additional letter 'n' in Acticin.</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Salex (Salicylic Acid) Cream 6%</p> <p><u>Usual Dose</u> Apply to affected area and cover the treated area at night; wash off in the morning with CeraVe cleanser. Once clearing is apparent, use Salex occasionally to maintain remission.</p>	<p><u>Orthographic</u> Both names start with the letter ‘S’. Additionally, the letter string ‘-li-’ in Sklice may appear similar to the letter string ‘-le-’ in Salex when scripted</p> <p><u>Overlap in the Route of Administration</u> Topical</p> <p><u>Overlap in the Dosage Form</u> Topical dosage form</p> <p><u>Strength</u> Single strength</p> <p><u>Overlap in the Frequency of Administration</u> One time</p> <p><u>Usual Dose</u> Use as directed</p>	<p><u>Orthographic</u> 3 upstrokes (‘S’, ‘k’, ‘l’) in Sklice vs. two upstrokes (‘S’, ‘l’) in Salex. Additionally, the cross stroke ‘x’ at the end of the name Salex may help differentiate the two names.</p> <p>Additionally, Salex is available in a 16 ounce jar and as a lotion in an eight ounce bottle. Both sizes are accompanied with a 12 ounce bottle of CeraVe Cleanser. Therefore, the varying packaging configurations may help differentiate the two products further.</p>

<p>Proposed name:</p> <p>Sklice (Ivermectin) Topical Lotion</p>	<p>Strength(s):</p> <p>0.5%</p>	<p>Usual dose:</p> <p>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.</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>Saline (Sodium Chloride) Nasal Spray, solution, or wound wash 0.65% (nasal spray) or 0.9% (wound wash)</p> <p><u>Usual Dose</u> Spray into nostril as needed.</p>	<p><u>Orthographic</u> Both names consist of 6 letters, start with the letter ‘S’ and end with the letter ‘e’. Additionally, the letter string ‘-lic-’ in Sklice may appear similar to the letter string ‘-lin-’ in Saline when scripted.</p> <p><u>Strength</u> Single strength</p> <p><u>Overlap in the Route of Administration</u> Topical (if Saline wash)</p> <p><u>Possible Overlap in the Frequency of Administration</u> Once</p> <p><u>Usual Dose</u> Both may be written as ‘as directed’.</p>	<p><u>Orthographic</u> 3 upstrokes (‘S’, ‘k’, ‘l’) in Sklice vs. two upstrokes (‘S’, ‘l’) in Saline. Additionally, a product descriptor such as solution, wash, nasal spray or spray will most likely follow ‘Saline’ which can further help differentiate the two names.</p> <p><u>Dosage Form</u> Lotion vs. nasal spray or wash</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode
<p>Silvadene (Silver Sulfadiazine) Cream, 1%</p> <p><u>Usual Dose</u> Apply to burn after cleansed and debride once or twice daily to a thickness of 1/16 inches.</p>	<p><u>Orthographic</u> Both names start with the letter ‘S’, end with the letter ‘e’, and share the upstroke ‘l’ in the 3rd position.</p> <p><u>Overlap in the Route of Administration</u> Topical</p> <p><u>Overlap in the Dosage Form</u> Topical dosage form</p> <p><u>Possible Overlap in the frequency of Administration</u> Once</p> <p><u>Strength</u> Single strength</p> <p><u>Usual Dose</u> Use as directed</p>	<p><u>Orthographic</u> The name Silvadene appears longer than Sklice when scripted because of the extra letters ‘e’, ‘n’, and ‘e’ in Silvadene.</p>

Proposed name: Sklice (Ivermectin) Topical Lotion	Strength(s): 0.5%	Usual dose: Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp; rinse off with water after 10 minutes.
Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion	Causes (could be multiple)	Prevention of Failure Mode

(b) (4)

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/s/

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