

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**210895Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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## PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

**\*\*\* This document contains proprietary information that cannot be released to the public\*\*\***

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<b>Date of This Review:</b>	April 9, 2018
<b>Application Type and Number:</b>	NDA 210895
<b>Product Name and Strength:</b>	Welchol (colesevelam hydrochloride) chewable bar, 3.75 g
<b>Product Type:</b>	Single Ingredient
<b>Rx or OTC:</b>	Rx
<b>Applicant/Sponsor Name:</b>	Daiichi Sankyo, Inc.
<b>Panorama #:</b>	2018-20331599
<b>DMEPA Safety Evaluator:</b>	Susan Rimmel, PharmD
<b>DMEPA Team Leader:</b>	Hina Mehta, PharmD
<b>DMEPA Associate Director (Acting):</b>	Mishale Mistry, PharmD, MPH

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## 1 INTRODUCTION

This review evaluates the proposed proprietary name, Welchol, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A, respectively. The Applicant did not submit an external name study for this proposed proprietary name.

### 1.1 REGULATORY HISTORY

Welchol (colesevelam hydrochloride) tablet, 625 mg (NDA 021176) and capsule, 375 mg (NDA 021141) were approved on May 26, 2000. In addition, Welchol for oral suspension, 1.875 g and 3.75 g single-dose packets (NDA 022362) was approved on October 2, 2009.

On October 30, 2017, the Applicant submitted a 505(b)(1) original NDA, seeking approval for a new oral dosage form, chewable bar, in a 3.75 g strength (NDA 210895). Thus, the Applicant submitted the name, Welchol (b) (4) for review on January 16, 2018.

We submitted an information request on January 30, 2018, to clarify if the Applicant intended (b) (4) as a modifier for the root name, Welchol. The Applicant submitted a proprietary name Amendment on February 7, 2018, indicating the proposed proprietary name is Welchol, and no modifier is being proposed.

### 1.2 PRODUCT INFORMATION

The following product information is provided in the original NDA seeking approval of the new dosage form received on October 30, 2017, and the proprietary name submission received on February 7, 2018.

<b>Table 1. Relevant Product Information for Welchol</b>				
<b>Product</b>	<b>Welchol (NDA 210895)</b>	<b>Welchol (NDA 021176)</b>	<b>Welchol (NDA 021141)</b>	<b>Welchol (NDA 022362)</b>
<b>Initial Approval Date</b>	N/A – proposed	May 26, 2000		October 2, 2009
<b>Intended Pronunciation</b>	\wel-kôl			
<b>Active Ingredient</b>	colesevelam hydrochloride			
<b>Indication of Use</b>	Adjunct to diet and exercise to: <ul style="list-style-type: none"><li>• reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin)</li></ul>			

	<ul style="list-style-type: none"> <li>• reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy</li> <li>• improve glycemic control in adults with type 2 diabetes mellitus</li> </ul>			
<b>Route of Administration</b>	oral			
<b>Dosage Form</b>	Chewable bar	Tablet	Capsule	For oral suspension
<b>Strength</b>	3.75 g  (available in a chocolate flavor, strawberry flavor, and caramel flavor)	625 mg	375 mg	<ul style="list-style-type: none"> <li>• 1.875 g</li> <li>• 3.75 g</li> </ul>
<b>Dose and Frequency</b>	1 bar once daily with a meal	6 tablets once daily or 3 tablets twice daily with a meal and liquid	10 capsules once daily or 5 capsules twice daily with a meal and liquid	1 single-dose 3.75 g packet once daily or 1 single-dose 1.875 g packet twice daily mixed with ½ to 1 cup (4 to 8 ounces) of water, fruit juice, or diet soft drinks; take with a meal
<b>How supplied</b>	Carton containing 30 (b) (4) chewable bars in a foil packet	180 count bottles	N/A (never marketed)	1.875 g: carton containing 60 single-dose packets  3.75 g: carton containing 30 single-dose packets
<b>Storage</b>	25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature] Protect from moisture.	25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature] Brief exposure to 40°C (104°F) does not adversely affect	Unknown	25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature] Protect from moisture.

		the product. Protect from moisture.		
<b>Reference Listed Drug/Reference Product</b>	N/A	Yes	No	Yes

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's 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*

There is no USAN stem present in the proprietary name.<sup>a</sup>

#### 2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Welchol, is derived from the words *well* and *cholesterol*. This proprietary name is comprised of a single word that does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

#### 2.2.3 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE January 29, 2018, e-mail, DMEP did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

#### 2.2.4 *Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities*

The proposed product, Welchol chewable bar, will be available in a 3.75 g strength. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names with strength overlap and potential orthographic, spelling, and phonetic similarities with Welchol

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<sup>a</sup> USAN stem search conducted on March 8, 2018.

chewable bar include Welchol 3.75 g for oral suspension. We evaluate multiple dosage forms under a single proprietary name in Section 2.2.6. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

### 2.2.5 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving *Welchol* that would be relevant for this review.

<b>Table 2. FAERS Search Strategy</b>	
<b>Search Date</b>	March 9, 2018
<b>Drug Name</b>	Welchol [product name] Colesevelam; colesevelam hydrochloride [product active ingredient and active ingredient] *Welchol* [product verbatim]
<b>Event PT</b>	Medication Error
<b>Event (MedDRA Terms)</b>	<p><b>DMEPA Official PNR Name Confusion Search Terms Event List:</b></p> <p>Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR</p> <p>Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED</p>

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, 177 reports were not included in the final analysis for the following reasons: 160 cases described drug administration errors not related to name confusion, 15 cases described drug prescribing errors (1 related to a presumed contraindication, 1 related to a presumed misdiagnosis, 1 for the wrong patient, and 12 improper dose cases related to intentional misuse resulting in 8 underdosages, 1 overdose, 2 wrong frequencies, and 1 wrong frequency for the wrong patient), and 2 cases described medication errors that we determined to be adverse drug events.

Following exclusions, the search yielded two (n = 2) relevant cases.

One case described a dispensing error where the patient received Welchol 625 mg tablets instead of Renagel 800 mg tablets. The case narrative suggests that staffing and distractions were a contributing factor to the error. The case does not specify if name confusion was a root cause of the dispensing error.

One case describes the potential for look-alike/sound-alike similarity between the names and strengths Welchol 625 mg and carvedilol 6.25 mg when scripted. No actual errors of name confusion were reported in the case narrative and none were identified in the excluded cases described above.

See Appendix A2 for more information.

### ***2.2.6 Multiple Dosage Forms Under a Single Proprietary Name***

Welchol is currently marketed as a 625 mg tablet (NDA 021176) and a 1.875 g and 3.75 g for oral suspension single-dose packet (NDA 022362).<sup>b,c</sup> The Applicant proposes a new chewable bar oral dosage form, available in a 3.75 g strength (NDA 210895), to be marketed under the same proprietary name, Welchol, as the currently approved products.

We considered the appropriateness of using the same proprietary name, Welchol, for the proposed 3.75 g chewable bar. The currently marketed Welchol products share the same active ingredient, indication, and route of administration. There is overlap in strength (3.75 g) between the chewable bar and the oral suspension dosage form; however, the dose and frequency are the same for both dosage forms. Therefore, the proposed 3.75 g chewable bar does not pose any new risks for strength and dose confusion when compared to currently marketed dosage forms. It is common and accepted practice to have a product line with multiple dosage forms managed under a shared proprietary name within a single package insert. In this case, the residual risk of wrong administration technique and confusion between the dosage forms may be mitigated through labels and labeling intervention. Furthermore, we have not identified any medication errors involving name confusion with the proprietary name, Welchol (See Section 2.2.5).

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<sup>b</sup> We note the Applicant proposes to remove all references to the 1.875 g for oral suspension strength in the Prescribing Information with this application submission.

<sup>c</sup> The 375 mg capsule has never been marketed.

Therefore, given the precedence for using this naming convention and the absence of any postmarketing cases of name confusion involving the proprietary name, we find the Applicant's proposal to market the chewable bar with the same proprietary name, Welchol, acceptable.

### ***2.2.7 Communication of DMEPA's Analysis at Midpoint of Review***

DMEPA communicated our findings to DMEP via e-mail on April 2, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on April 2, 2018, they stated no additional concerns with the proposed proprietary name, Welchol.

## **3 CONCLUSION**

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your submission, received on October 30, 2017, and February 7, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCES

1. **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.

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

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

### *Drugs@FDA*

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States 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* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at [http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther\\_biological](http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological)).

### *RxNorm*

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#>).

### *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.

### 3. *Electronic Drug Registration and Listing System (eDRLS) database*

The electronic Drug Registration and Listing System (eDRLS) was established to support the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
  - a. **Preliminary Assessment:** 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.) See prescreening checklist below in Table 2\*. 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.<sup>d</sup>

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

**\*Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
<b>Y/N</b>	<b>Is the proposed name obviously similar in spelling and pronunciation to other names?</b>
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
<b>Y/N</b>	<b>Are there inert or inactive ingredients referenced in the proprietary name?</b>
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
<b>Y/N</b>	<b>Does the proprietary name include combinations of active ingredients?</b>
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
<b>Y/N</b>	<b>Is there a United States Adopted Name (USAN) stem in the proprietary name?</b>
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
<b>Y/N</b>	<b>Is this proprietary name used for another product that does not share at least one common active ingredient?</b>
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
<b>Y/N</b>	<b>Is this a proprietary name of a discontinued product?</b>
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

- b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:
- Highly similar pair: combined match percentage score  $\geq 70\%$ .
  - Moderately similar pair: combined match percentage score  $\geq 55\%$  to  $\leq 69\%$ .
  - Low similarity: combined match percentage score  $\leq 54\%$ .

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of  $\geq 70$  percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
  - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names<sup>e</sup>. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
  - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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<sup>e</sup> Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

- c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

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.

- d. 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.

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.

**Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is  $\geq 70\%$ ).**

<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.</p>			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
<b>Y/N</b>	<p>Do the names begin with different first letters?</p> <p><i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i></p>	<b>Y/N</b>	<p>Do the names have different number of syllables?</p>
<b>Y/N</b>	<p>Are the lengths of the names dissimilar* when scripted?</p> <p><i>*FDA considers the length of names different if the names differ by two or more letters.</i></p>	<b>Y/N</b>	<p>Do the names have different syllabic stresses?</p>
<b>Y/N</b>	<p>Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names?</p>	<b>Y/N</b>	<p>Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</p>
<b>Y/N</b>	<p>Is there different number or placement of cross-stroke or dotted letters present in the names?</p>	<b>Y/N</b>	<p>Across a range of dialects, are the names consistently pronounced differently?</p>
<b>Y/N</b>	<p>Do the infixes of the name appear dissimilar when scripted?</p>		
<b>Y/N</b>	<p>Do the suffixes of the names appear dissimilar when scripted?</p>		

**Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is  $\geq 55\%$  to  $\leq 69\%$ ).**

Step 1	<p>Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"><li>• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.</li><li>• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.</li><li>• Similar sounding doses: 15 mg is similar in sound to 50 mg</li></ul>
Step 2	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <b>with</b> overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</li> <li>• Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters.</li> <li>• Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), is there a different number or placement of upstroke/downstroke letters present in the names?</li> <li>• Is there different number or placement of cross-stroke or dotted letters present in the names?</li> <li>• Do the infixes of the name appear dissimilar when scripted?</li> <li>• Do the suffixes of the names appear dissimilar when scripted?</li> </ul>	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> <li>• Do the names have different number of syllables?</li> <li>• Do the names have different syllabic stresses?</li> <li>• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?</li> <li>• Across a range of dialects, are the names consistently pronounced differently?</li> </ul>
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**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).**

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

## **Appendix A1: Description of FAERS**

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm>.

## **Appendix A2: FAERS Search Results**

A summary of the relevant cases is provided in the table below.

Reported Error	# of Cases	Case Narrative and Reported Root Cause(s)/Contributing Factor(s)
Confusion between Welchol 625 tablets and Renagel 800 mg tablets	1	n = 1: <i>drug dispensing error</i> <ul style="list-style-type: none"><li>• Patient received Welchol 625 mg tablets instead of Renagel 800 mg tablets. Case narrative indicates it was a stressful day, lead technician was on vacation, and staff was upset. Authorities were investigating accusations of drug diversion involving the lead clerk. Staff was working to gather information and documentation for the investigation alongside their regular duties. <i>Narrative does not specify if name confusion was a root cause of the dispensing error.</i></li></ul>
Confusion between Welchol 625 mg and established name carvedilol 6.25 mg	1	n = 1: <i>wrong drug/strength error</i> (potential error) <ul style="list-style-type: none"><li>• Potential for look-alike/sound-alike similarity between the names and strengths Welchol 625 mg and carvedilol 6.25 mg when scripted. <i>No actual errors of name confusion reported in the case narrative and none identified in the excluded cases of our search.</i></li></ul>

A listing of the relevant FAERS case numbers is provided in the table below.

Case Count	FAERS Case #	Version	Manufacturer Control #
1	5956538	1	N/A (direct report)
2	6289699	1	N/A (direct report)

**Appendix I:** Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	AGGRASTAT
2.	Anti Aging
3.	Antibacterial Skin Cleanser
4.	Calcium
5.	Clorazepate Dipotassium
6.	CRYSTAL MIRACLE MULTI
7.	Double S Essence Clean
8.	DR MYERS WATER KEEP SKINS
9.	Expression
10.	Gentle Therapy Treatment
11.	Hi-Tech
12.	Hydromarine
13.	In-111 DTPA
14.	La Creme Plus
15.	Mirapex
16.	PLACENTA EX DAY
17.	Pramipexole Dihydrochloride
18.	Regemarine
19.	Retin
20.	Seborrheic
21.	Supreme
22.	Trelstar
23.	Triton AB-741
24.	UV MILD SUN BLOCK
25.	Vita

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/s/  
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SUSAN RIMMEL  
04/09/2018

HINA S MEHTA  
04/09/2018

MISHALE P MISTRY  
04/09/2018

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**PROPRIETARY NAME MEMORANDUM**

Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE)  
Center for Drug Evaluation and Research (CDER)

**\*\*\* This document contains proprietary information that cannot be released to the public\*\*\***

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<b>Date of This Review:</b>	March 18, 2019
<b>Application Type and Number:</b>	NDA 210895
<b>Product Name and Strength:</b>	Welchol (colesevelam hydrochloride) chewable bars, 3.75 g
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Prescription (Rx)
<b>Applicant/Sponsor Name:</b>	Daiichi Sankyo, Inc.
<b>Panorama #:</b>	2019-29937667
<b>DMEPA Safety Evaluator:</b>	Madhuri R. Patel, PharmD
<b>DMEPA Team Leader:</b>	Sevan Kolejian, PharmD, MBA

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## **1 INTRODUCTION**

This memorandum is to reassess the proposed proprietary name, Welchol, which was found conditionally acceptable under NDA 210895 on April 9, 2018.<sup>a</sup> We note that all product characteristics remain the same.

## **2 METHODS AND DISCUSSION**

### **2.1 MISBRANDING ASSESSMENT**

The Office of Prescription Drug Promotion (OPDP) determined that Welchol would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Welchol.

### **2.2 SAFETY ASSESSMENT**

For re-assessment of the proposed proprietary name, DMEPA 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. Additionally, DMEPA searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The March 12, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Welchol. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Welchol.

### **2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW**

DMEPA communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on March 18, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on March 18, 2019, they stated no additional concerns with the proposed proprietary name, Welchol.

## **3 CONCLUSION**

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Welchol, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

### **3.1 COMMENTS TO DAIICHI SANKYO, INC.**

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

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<sup>a</sup> Rimmel, S. Proprietary Name Review for Welchol (colesevelam hydrochloride) chewable bars (NDA 210895). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 APR 09. Panorama No.: 2018-20331599.

If any of the proposed product characteristics as stated in your submission, received on October 3, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

#### **4 REFERENCE**

- 1. USAN Stems** (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

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/s/  
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MADHURI R PATEL  
03/18/2019 08:46:30 AM

SEVAN H KOLEJIAN  
03/18/2019 10:37:28 AM