

## APPENDICES

### Appendix A:

The Medication Error Staff consider the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. We also compare the spelling of the proposed proprietary name with the proprietary and established name of existing and proposed drug products because similarly spelled names may have greater likelihood to sound similar to one another when spoken or look similar to one another when scripted. The Medication Error Staff also examine the orthographic appearance of the proposed name using a number of different handwriting samples. Handwritten communication of drug names has a long-standing association with drug name confusion. Handwriting can cause similarly *and* dissimilarly spelled drug name pairs to appear very similar to one another and the similar appearance of drug names when scripted has led to medication errors. The Medication Error Staff apply their expertise gained from root-cause analysis of such 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), along with other orthographic attributes that determine the overall appearance of the drug name when scripted (see detail in Table 1 below). Additionally, since verbal communication of medication names is common in clinical settings, the Medication Error Staff compare the pronunciation of the proposed proprietary name with the pronunciation of other drug names. If provided, we will consider the Sponsor's intended pronunciation of the proprietary name. However, because the Sponsor has little control over how the name will be spoken in practice, we also consider a variety of pronunciations that could occur in the English language.

**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		
	Potential causes of drug name similarity	Attributes examined to identify similar drug names	Potential Effects
Look-alike	Similar spelling	Identical prefix Identical infix Identical suffix Length of the name Overlapping product characteristics	<ul style="list-style-type: none"> <li>Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication</li> <li>Names may look similar when scripted and lead to drug name confusion in written communication</li> </ul>
	Orthographic similarity	Similar spelling Length of the name Upstrokes Downstrokes Cross-strokes	<ul style="list-style-type: none"> <li>Names may look similar when scripted, and lead to drug name confusion in written communication</li> </ul>

		<b>Dotted letters</b> <b>Ambiguity introduced by scripting letters</b> <b>Overlapping product characteristics</b>	
<b>Sound-alike</b>	<b>Phonetic similarity</b>	<b>Identical prefix</b> <b>Identical infix</b> <b>Identical suffix</b> <b>Number of syllables</b> <b>Stresses</b> <b>Placement of vowel sounds</b> <b>Placement of consonant sounds</b> <b>Overlapping product characteristics</b>	<ul style="list-style-type: none"> <li>• Names may sound similar when pronounced and lead to drug name confusion in verbal communication</li> </ul>

**Appendix B:**

**ZolpiMist CDER Prescription Study Responses**

<b>Outpatient Prescription</b>	<b>Inpatient Medication Order</b>	<b>Voice Prescription</b>
Fulpomist	Zofrident	Zolfomist
Zalpmimist	Zolpident	Zolimus
Zalpomist	Zolpident	Zolpamist
Zalpomist	Zolpidient	Zolpamist
Zalpomist	Zolpidint	
Zalpomist	Zolpidint	
Zalprimist	Zolpidint	
Zalprimist	Zolpidit	
Zalprimist	Zolpidint	
Zalprimist	Zolpidint	
Zalpromist	Zolpidlit (or Zolpidint)	
Zalpromist	Zolpimist	
Zalpumist	Zoxident	
Zalpumist		
Zalpumist		
Zolpomist		
Zolpumist		

**Appendix C:** Names lacking convincing look-alike and/or sound-alike similarities with ZolpiMist

Proprietary Name	Similarity to ZolpiMist
Nitromist	Look
Evamist	Look
Vitamist	Look
Calomist	Look
Calahist	Look
Zoladex	Sound
Solaquin	Sound
Sulfatrim	Sound

**Appendix D:** Product with a different context of use than ZolpiMist

Proprietary Name	Similarity to ZolpiMist	Description
Zolimid	Look	Veterinary medicine product used to treat babesiosis, anaplasmosis, and ehrlichiosis. Also listed as a trademarked product of Cytos Pharmaceuticals, characterized as "pharmaceutical preparations for tissue protection, namely anti-inflammatories and anti-oxidants".

**Appendix E:** Products discontinued from the U.S. market

Proprietary Name	Similarity to ZolpiMist	Generics available?
Nolahist (phenindamine) tablets	Look	No
Soltamox (tamoxifen) oral solution	Sound	No
Coldmist line of products (guaifenesin/pseudoephedrine or guaifenesin/pseudoephedrine/dextromethorphan)	Look and Sound	Yes; combinations of these ingredients are available under a variety of names.

**Appendix F: Proprietary names used only in Foreign Countries**

<b>Proprietary Name</b>	<b>Similarity to ZolpiMist</b>	<b>Country</b>	<b>Description</b>
Zolpinox	Look	Germany	Zolpidem
Zolpi-Med	Look	Switzerland	Zolpidem
Zolpramex	Look	Brazil	Omeprazole

**Appendix G: Established name of the subject of this application**

<b>Established Name</b>	<b>Similarity to ZolpiMist</b>
Zolpidem	Look and Sound

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**Appendix H:** Potential confusing names with numerical overlap in strength, dose, or frequency

Failure Mode: Name confusion	Causes (could be multiple)	Effects
<p><b>ZolpiMist</b> (zolpidem tartrate) <b>Oral Spray</b></p>	<p><b>5 mg per metered actuation</b></p>	<p><b>Usual dose: 10 mg (2 actuations) sprayed directly into the mouth, over the tongue, at bedtime</b></p>
<p><b>Zomig-ZMT</b> (zolmitriptan) orally disintegrating tablets 2.5 mg, 5 mg</p>	<p>Overlapping strengths (5 mg per metered actuation vs. 5 mg tablet)</p>	<p>Orthographic differences as well as differing product characteristics minimize the likelihood of medication errors in the usual practice settings.</p> <p><i>Rationale:</i></p> <p>Although the names share the beginning letters 'Zo' and both names contain the letters 'mi', the remaining letters do not overlap and do not look similar.</p> <p>ZolpiMist is dosed every evening, as opposed to Zomig-ZMT, which is dosed at onset of migraine headache.</p>
<p><b>Topamax</b> (topiramate) Tablets: 25 mg, 50 mg, 100 mg, 200 mg, Sprinkle Capsules: 15 mg, 25 mg</p>	<p>Numerically similar strengths: 5 mg per metered actuation vs. 50 mg tablet</p>	<p>Differing product characteristics minimize the likelihood of medication errors in the usual practice settings.</p> <p><i>Rationale:</i></p> <p>Although the beginning letters of the names may look similar ('Zolp' vs. 'Top'), the endings of the names help to distinguish them ('imist' vs. 'amax').</p> <p>Topamax is available in two dosage forms: tablets and sprinkle capsules. Therefore, in order for a prescription for Topamax to be filled, the dosage form would have to be specified. In contrast, ZolpiMist is available in only one dosage form. Further, Topamax is dosed twice daily as opposed to ZolpiMist which is dosed at bedtime.</p>
<p><b>Xopenex</b> (levalbuterol) HFA Inhalation Aerosol:  Inhalation Solution: 0.31 mg, 0.63 mg, 1.25 mg unit dose vials</p>	<p>Overlapping dose: (2 actuations vs. 2 inhalations of the aerosol)</p>	<p>Phonetic differences as well as differing product characteristics minimize the likelihood of medication errors in the usual practice settings.</p> <p><i>Rationale:</i></p> <p>The 'Zolp' sound of ZolpiMist can sound like the 'Xop' of Xopenex. However, the remaining syllables in the names ('imist' vs. 'enex') help to distinguish them.</p> <p>Xopenex is available in three dosage forms: HFA inhalation aerosol, inhalation solution, and inhalation solution concentrate. Further, the inhalation solution is</p>

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<p>(3 mL)  <b>Inhalation Solution Concentrate:</b>  1.25 mg per 0.5 mL unit dose vials</p>		<p>available in three concentrations. Therefore, in order for a prescription for Xopenex to be filled, the dosage form, and possibly the concentration, would have to be specified. In contrast, ZolpiMist is available in only one dosage form and one concentration. Additionally, the dosing for these products helps to distinguish them. Xopenex inhaler is dosed every 4 to 6 hours and the inhalation solution and concentrate are dosed three times daily, every 6 to 8 hours. ZolpiMist is dosed daily at bedtime.</p>
<p><b>Zolinza</b>  (vorinostat)  Capsule: 100 mg</p>	<p><b>Overlapping frequency</b>  (once daily); available in a single strength</p>	<p>Orthographic differences as well as differing product characteristics minimize the likelihood of medication errors in the usual practice settings.</p> <p><i>Rationale:</i></p> <p>Although the names share the beginning letters 'Zol', the remaining letters do not overlap and do not look similar.</p> <p>There is no overlap in the dosage of these products. Zolinza is dosed at 400 mg orally once daily with food. ZolpiMist is dosed at 10 mg or 2 metered actuations at bedtime.</p>

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