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FDA’s POCA Scoring System for New Drug Names

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In the Draft Guidance, FDA proposes weighing the combined score (generally, an average of the orthographic and phonetic scores) and classifying the results into one of three tiers—each with a different framework for analyzing the potential safety of the proposed name. Then, within each framework, FDA assigns more subjective criteria along with a sense of "burden" or "weight" that the proposed name must overcome. These frameworks are summarized in the chart below:
In spite of FDA's best efforts, medication errors continue to burden our health care system. These errors can occur for a variety of reasons, ranging from pharmacists incorrectly interpreting the letters or words on a hand-written prescription, to nurses incorrectly interpreting physician instructions for hospitalized patients, and are estimated to cause approximately 7,000 deaths each year in the United States alone.

The United States Food and Drug Administration ("FDA") recently unveiled a new initiative to reduce medication errors by evaluating product names using a Phonetic and Orthographic Computer Analysis ("POCA"). In a May 2014 Draft Guidance, entitled *Best Practices in Developing Proprietary Names for Drugs*, FDA notes that its intentions are "to develop proprietary names that do not cause or contribute to medication errors or otherwise contribute to the misbranding of the drug."

The Draft Guidance offers certain rules and factors for increasing the safety profile of a proposed name. For example, FDA states that the name should not include product attributes (such as dosage form) because future modifications may create a greater likelihood of errors. The Draft Guidance contains other straightforward rules for avoiding confusion and promoting safe use of pharmaceutical products.

For purposes of comparing drug names, FDA's Draft Guidance attempts to give objective and quantifiable guidance in a field that inherently lends itself to at least some subjectivity. Specifically, the Draft Guidance emphasizes the role of the POCA score in early screening processes and determining what level of scrutiny a proposed name must bear.

The POCA system comprises lists of pre-existing pharmaceutical product names (along with other relevant information, e.g., dosage). The database user enters the proposed name in the POCA system and queries the name against drug reference databases through an algorithm that weighs orthographic and phonetic similarities. This query results in a list of the most similar pre-existing names along with the combined POCA score for each result. The higher the POCA score for an entry, the more similar the proposed name is to that pre-existing name, and the less likely that FDA will accept the proposed name.

The POCA score attempts to account for all aspects of a written prescription. Thus, in addition to the resemblance of syllables and letters, the score will account for the dose that must be written on the prescription, as well as any suffix such as "ER" or product concentration that is necessarily part of the prescription or physician instructions.

similar sounding doses (e.g., 15 mg is similar in sound to 50 mg).

Step 2 – Checklist of questions. Affirmative answers to some questions may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses:

Do the names begin with the first letter? (note that certain letter may still be confused when scripted)

- Are the lengths of the names dissimilar when scripted? (FDA considers the length to be different if the names differ by two or more letters in length)
- Considering variations in scripting of some letters, is there a different number or placement of upstroke/downstroke letters present in the names?
- Is there different number or placement of cross-stroke or dotted letters present in the names?
- Do the infixes (group of letters in the middle of the name) of the name appear dissimilar when scripted?
- Do the suffixes of the names appear dissimilar when scripted?
- Do the names have different number of syllables?
- Do the names have different syllabic stresses?
- Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
- Across a range of dialects, are the names consistently pronounced differently?

70 or more	High Similarity	For highly similar names, FDA takes the position that differences in product characteristics often cannot mitigate the risk of a medication error, including differences in product strength and dose. FDA proposes several questions (the same questions as Step 2 above) that, where some are answered in the affirmative, may suggest that the differences in the names may render them less likely to confusion, provided that the pair do not share a common strength or dose: • Do the names begin with the first letter? (note that certain letter may still be confused when scripted) • Are the lengths of the names dissimilar when scripted? (FDA considers the length to be different if the names differ by two or more letters in length) • Considering variations in scripting of some letters, is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes (group of letters in the middle of the name) of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted? • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are

		the names consistently pronounced differently?
49 or less	Low Similarity	Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable absent indications of potential confusion (e.g., overlap or similarity in strength and dose, prescription simulation study suggests that the name is likely to be misinterpreted). In these instances, FDA will evaluate the names under the "moderate similarity" framework below.
50 to 69	Moderate Similarity	Moderately similar names with overlapping or similar doses represent an area of concern for FDA. Under the framework, the ability of other product characteristics to mitigate confusion may be limited when the strength or dose overlaps.

Critics and commentators of the Draft Guidance generally applaud the document as a first step in achieving more predictable results for FDA approval. To be sure, there are still many open questions about the weight and meaning of the POCA score in the ultimate approval process. What is clear, however, is that any proprietary name development process should incorporate a POCA score analysis and consider the potential risks identified in FDA's Draft Guidance.

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Step 1 – Review the Dosage and Administration and Storage and Handling sections of the prescribing information or the Drug Facts label to determine if strengths and doses of the name pair overlap or are very similar, keeping in mind alternative expressions of dose, trailing or deleting zeros (e.g., 10 mg is similar in appearance to 100 mg), and