Biotechnology Industry Organization

July 28th, 2014

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2014-D-0622: Draft Guidance for Industry on *Best Practices in Developing Proprietary Names for Drugs*

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA, the Agency) for the opportunity to submit comments on the Draft Guidance for Industry on *Best Practices in Developing Proprietary Names for Drugs*.

BIO represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

GENERAL COMMENTS:

BIO commends FDA on releasing this Draft Guidance, which will help guide Sponsors as they choose proprietary names that will minimize the potential for medication errors or misbranding.

In the Draft Guidance FDA provides recommended testing methods for Sponsors, however, the Draft Guidance indicates that the Agency will still perform internal tests using the same methodology. FDA does not currently repeat test methods in other areas (for example, stability) when a Sponsor follows the recommended test methods. As such, there should be no need for FDA to duplicate the testing if a Sponsor follows the recommended methodology in its submission. We recognize that FDA may reanalyze the data—as it does with other data sets—but creating separate, duplicative data is a poor utilization of limited Agency resources. BIO also believes the Agency's request that Sponsors test a minimum of 20 scenarios, each with 2-5 participants, is overly burdensome for the Sponsor and will not improve the quality of proprietary name review.

FDA recommends that Sponsors screen proposed names through the Agency's Phonetic and Orthographic Computer Analysis (POCA) system. The Draft Guidance states that a

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name in the "moderately similar pair" category (≥50% to ≤ 69%) with overlapping attributes—such as similar strengths or doses—would likely be rejected by FDA. BIO would like to note, however, that the average POCA score for products approved in 2013 was 62%. As such, without further clarification, FDA's recommendation seems arbitrary. The Agency should also consider type of drug and its context of use when considering proprietary names.

We further believe it would be useful to Sponsors if FDA suggested resources for names of foreign products in Appendix A. It would also be helpful if the Agency addressed situations where a proposed name is similar to an herbal/natural product or an unapproved product.

With the trend toward e-prescribing—where 73% of office-based physicians are e-prescribing[1]—there should be a greater emphasis on the technological aspect of prescribing than is currently in the Draft Guidance. As such, we believe it would be helpful for FDA to consider incorporating "autocorrect" and typing errors in its methodology.

Further, the Draft Guidance does not contain a recommended methodology to test a proposed name for promotional concerns. As drug names are often rejected due to the promotional nature of the name, BIO suggests providing recommendations on a specific methodology to test names for promotional concerns, either in this Draft Guidance or in a companion guidance. Additionally, we recommend that the Division of Medical Error Prevention and Analysis (DMEPA) should include the review (with appropriately redacted confidential company information) in the Summary Basis of Approval.

The Draft Guidance also does not adequately cross-reference the timelines for trade name review, which are detailed in the *PDUFA Reauthorization Performance Goals and Procedures: Fiscal Years 2013-2017* and the FDA Guidance on *Contents of a Complete Submission for the Evaluation of Proprietary Names*. Under the PDUFA program, FDA has committed to review 90 percent of IND-stage proprietary name submissions filed within 180 days of receipt and within 90 days during the NDA/BLA review. BIO recommends that in some instances, such as for Breakthrough Therapy Designated products, FDA should strive to expedite the review of the trade name within 45 days, consistent with the "all-hands-on deck" approach to Breakthrough Therapy product development and review.

Lastly, BIO recommends that the Draft Guidance should be expanded to include additional information on what will be conveyed to a Sponsor if a proprietary name is rejected, as well as stating that the Sponsor will have the opportunity for a teleconference with FDA to ask questions and clarify the written correspondence, and discuss potential solutions to address a rejection.

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[1] *2013 National Progress Report and Safe-Rx Rankings*, Surescripts: http://surescripts.com/docs/default-source/national-progress-reports/surescripts_2013_national_progress_report.pdf?sfvrsn=2

CONCLUSION:

BIO appreciates this opportunity to comment on the draft guidance on *Best Practices in Developing Proprietary Names for Drugs.* Specific, detailed comments are included in the following chart. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Managing Director, Science and Regulatory Affairs
Biotechnology Industry Organization (BIO)

SPECIFIC COMMENTS

SECTION	ISSUE	PROPOSED CHANGE
I. INTRODUCTION		
Footnote 6:	Footnote 6 states that "…this third guidance on best practices for developing and selecting proprietary names is intended to complement our existing guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*." The guidance referenced in the footnote states that "Applicants may include any assessments of the proprietary name…However, submission of such assessments will neither substitute for submission of the other information described in this guidance as constituting a complete submission, nor will FDA consider a submission incomplete because this information is not provided." It is not clear whether the FDA now considers the assessment information necessary for a complete submission, or this information will continue to be optional as currently described in the Complete Submission Guidance.	We ask FDA to clarify whether or not the assessment information is necessary for a complete submission or if this information will remain optional.
II. BACKGROUND		
Lines 74-75:	The statement "All the evaluation methods	In the spirit of full transparency, FDA should provide a

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	proposed by FDA were judged by the participating expert panel to be complementary and of value in the proprietary naming process," suggests a confluence of entities and events that resulted in this document but does not divulge any specifics.	footnote that reveals the persons and organization(s) who comprised the expert panel, and if possible the references to meeting minutes or event notes documenting this concurrence so that Sponsors can fully understand the history and processes leading to this Draft Guidance content.
III. RECOMMENDATIONS FOR PRESCREENING PROPRIETARY NAME CANDIDATES		
E. UNITED STATES ADOPTED NAME (USAN) STEMS		
Lines 142-155:	FDA's position on the use of USAN stems in proprietary names in non-stem positions remains unclear. As the list of USAN stems continues to grow and with only 26 letters in the alphabet, Sponsors are finding it increasingly difficult to create proprietary names that do not contain a USAN stem from one of the many pharmacological drug classes.	We suggest including a statement from the September 2008 Concept Paper to the current Draft Guidance that states, "Conversely, if the same letter sequence that makes up the USAN stem appears in an alternate position in the proposed name, it may be acceptable."
G. REUSE OF PROPRIETARY NAMES		
Lines 169-178:	The Draft Guidance does not discuss conditional approvals. If a Sponsor receives conditional approval for a proprietary name and never markets that drug/biologic, the assumption would be that the name could be considered for future use based on the current language	We suggest adding a sentence that clarifies the potential use of conditionally approved proprietary names that have never been used for a marketed product.

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	in the guidance.	
V. MISBRANDING REVIEW AND METHODS FOR EVALUATING SAFETY OF PROPOSED PROPRIETARY NAMES FOR DRUGS		
A. MISBRANDING REVIEW (OTHER THAN MEDICATION ERROR PREVENTION)		
Lines 438-449:	The Draft Guidance states "In determining whether a name is misleading, common morphological and semantic associations are considered along with *phonesthemes* (the sound of the name) and *phonosemantics* (meaning conveyed by the sound of the word) of the name." A review of name rejections due to misbranding in the last three years suggests that these concepts may not be new, although it appears this is the first time these terms are appearing. We are concerned that these terms still do not eliminate the variability and subjectivity in determining when the name (or part of the name) sounds like a word or implies a meaning that constitutes a claim. The subsequent example in lines 442-449 is not a clear illustration of these terms because it talks about the proposed name literally including the word "best," rather than some concatenation of letters that	FDA should operationally define how morphological and semantic associations, including *phonosthemes* and *phonosemantics*, are considered in misbranding review, so that it is transparent when a claim is unacceptable. For the sake of legibility, pronounceability, and memorability, proposed proprietary names will likely contain consonant/vowel strings that resemble English words or word parts, and not all such associations are considered misleading or promotional claims.

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	sounds like or means "best".	
B. SAFETY REVIEW		
Lines 524-526:	We are concerned that the following statement generally compels Sponsors to incorporate additional healthcare professionals as participants in studies involving specialty drugs, whereas in most cases they are not germane: "Even when evaluating proprietary names for specialty drugs, Sponsors should consider including primary care practitioners, pharmacists and nurses to probe which product names outside the specialty might cause error." This subtracts from limited resources available to conduct simulation studies using a broad array of scenarios with healthcare professionals who are directly relevant, and it adds a biased source of data that is open to different interpretations by the reviewer, whether it is the Sponsor or the Agency.	We propose FDA use the following rewording: "~~Even when evaluating proprietary names for specialty drugs, Sponsors should consider including primary care practitioners, pharmacists and nurses to probe which product names outside the specialty might cause error.~~ In rare instances where a specialty drug could be at risk for entering into broader health care contexts, Sponsors should consider including primary care practitioners, pharmacists, and nurses to probe which product names outside the specialty cause error."
Lines 538-539:	The Draft Guidance states that "…to minimize bias, a name should not be tested by the same participant more than once." We consider the results unbiased if the same participant participates in both the written and spoken scenarios as they are examining different aspects (visual	We recommend adding clarification and editing the statement to read: "However, to minimize bias, a name should ~~not be tested by the same participant more than once~~ be tested only once by the same participant in the written scenarios and

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	and audio) of the name.	spoken scenarios."
Lines 567-574 & Table 2 (p. 16)	The Draft Guidance states "All qualitative data derived from follow-up questioning should be coded and analysed based on verbatim responses from participants (see Table 2 for examples of verbatim responses grouped into categories). The verbatim responses might confirm or further describe a potential for confusion. More importantly, responses might identify additional names of concern that were not identified through a manual database or computational searches". While we agree with the point that qualitative responses from participants can provide valuable additional input for the study, we do not see the value in counting the number of "Yes" versus "No" responses and the number of look-alike/sound-alike citations of existing brand names for a proposed drug name as shown in Table 2. In particular, such counts can be misleading because they imply that a greater number of citations equal a higher risk of medication errors for a proposed name, which may not be true. Given there are thousands of existing drug names in the United States marketplace, most, if not all, proposed names have look-alike and/or sound-alike (LA/SA) brand names. The	We propose FDA use the following rewording: "All qualitative data derived from follow-up questioning should be ~~coded and analysed~~ compiled and examined based on verbatim responses from participants…" We ask FDA to display the example follow-up data in a way that reflects its best practices value, which is simply to show that pertinent healthcare professionals provide qualitative data in the form of verbatim comments generating sound-alike and/or look-alike brand names to be further evaluated in the research for likelihood of confusion.

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	counting of "Yesses" or LA/SA citations implies that there be a threshold point for which it becomes a significant concern, but the FDA has provided none.	
Lines 578-584:	FDA is suggesting that the Sponsor review their own medication error databases and published literature to identify relevant information about problems that lead to medication errors. Although this concept is not new, and we applaud the safety goal of learning from past medication errors in order to prevent them from recurring, in order to evaluate such data effectively more explanation is needed on the types of searches of Sponsors' databases and literature that would constitute due diligence, and how "relevant information" is to be identified from case reports and evaluated against a given proposed name. In short, the FDA recommends that Sponsors follow the Agency's process of using medication error data without fully disclosing the process itself, and there is no illustration for Sponsors to follow. One example where clarification is needed is the following: if the new product is a first-in-class new chemical entity that is not yet approved or marketed anywhere, are we correct in assuming there would be no medication error data to be considered?	FDA should clarify the types of medication error data to be considered and how relevant information is identified and applied to different circumstances, such as when the product is a new breakthrough therapy versus a line extension for a currently marketed prescription product versus a product already marketed in a foreign country. Illustrations for these different product scenarios will facilitate Sponsors following FDA's process in terms of what to look for and how to evaluate medication errors against a particular proposed proprietary name.

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Lines 607-610	FDA recommends that Sponsors use POCA to conduct orthographic and phonetic searches. Members have reported being unable to download the program to date from FDA due to technical issues.	FDA should provide an easily downloadable and user-friendly version of POCA.
Lines 612-614	The Draft Guidance states "If the proposed name contains a modifier, first enter the root proprietary name without the modifier and group the names as described below. Then repeat this process using the root name and modifier." What is/are the purpose(s) of performing a SA/LA search both ways? Additionally, is FDA using this method for analysis via POCA, whether or not the proposed drug name with modifier is significantly different from the root proprietary name?	FDA should explain the reason(s) for this method of evaluating a proposed proprietary name with and without a modifier, given that a comprehensive search and analysis of sound-alike and look-alike issues for the root proprietary name was conducted prior to product approval. Using a contrived or hypothetical example of a proposed proprietary name, FDA should illustrate how a list of sound-alike and/or look-alike brand names may change as a function of the modifier.
GLOSSARY		
Lines 740-747:	This section includes the Glossary terms, "Assimilation" and "Deletion". Although the general examples are somewhat helpful in illustrating these new terms, the wording suggests there is a defineable list of English letter/vowel concatenations that are most prone to one or both of these perceptual phenomena.	FDA should provide a list of common letter/vowel concatenations that are prone to assimilation and/or deletion, as well as clear direction on how Sponsors should use the this information given that FDA has incorporated these phenomena into its process for evaluating high-similarity name pairs (see Appendix D Table, page 30, row 1). Additional examples of English words that illustrate the concepts of assimilation and/or deletion would also be helpful.

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APPENDIX A		
Line 863:	The Draft Guidance advises Sponsors to assess name similarity using POCA designed by FDA and states that the system is publically available from FDA upon request.	We recommend adding information on whom to contact at FDA to request the POCA system.