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July 31, 2008

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: FDA Docket 2008N–0281: Pilot Program to Evaluate Proposed Name Submissions; Concept Paper; Public Meeting

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Food and Drug Administration (FDA) for the opportunity to submit comments on the proposed *Pilot Program to Evaluate Proposed Name Submissions.* BIO applauds the Agency's efforts to minimize the potential for medication errors caused by look-alike and sound-alike proprietary drug names by exploring "best practices" for external vetting of proposed names followed by FDA review of the submitted data.

BIO represents more than 1,200 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 technologies, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

BIO SUPPORTS THE GOALS OF THE PILOT PROGRAM:

For BIO member companies, patient safety and well being is the top priority. Biopharmaceutical companies perform extensive internal pre-review of proposed proprietary names prior to submission to FDA to minimize the potential for medication errors. Drug name confusion results in only a small subset of medication errors, but

given the complexity of the scientific or non-proprietary name of many drug products, including biologics, it is important to have clear and concise proprietary names to ensure appropriate prescribing and administration. However in recent years, a lack of established validated best practices for trademark evaluation and uncertainty regarding the respective roles and responsibilities of FDA and drug sponsors has resulted in significant inefficiencies in the trademark review process, leading to an excessively high trademark rejection rate. A trademark rejection late in the NDA/BLA review can be disruptive and costly, leading to additional review cycles and inefficient use of resources for sponsors and FDA.

BIO supports the overall goals of the pilot program, which seeks to assess a new paradigm for trademark evaluation in which the drug or biologic manufacturer conducts or sponsors the trademark evaluation based upon FDA's recommendations, followed by FDA review of the data generated. This model is more closely aligned with FDA's traditional role of reviewing sponsor-generated data, such as clinical data in drug marketing applications, and is consistent with recommendations of the Institute of Medicine and the Department of Health and Human Services (HHS) Advisory Committee on Regulatory Reform.[i, ii] By more clearly delineating roles and responsibilities for proprietary name evaluation, FDA and industry can eliminate redundancies in the review process and more efficiently allocate resources. Consistent recommendations for proprietary name evaluation can help to improve transparency in the review process, which may lead to a higher first cycle approval rate for proprietary names and decreased likelihood of medication errors caused by look-alike or sound-alike drug names.

PROPOSED METHODS MAY NOT CONSTITUTE "BEST PRACTICES":

While the trademark evaluation methodologies proposed in the concept paper may lead to increased consistency, BIO notes that the proposed techniques have not been independently validated. The pilot program as currently configured is based in part on the presumption that FDA's current process is effective in identifying unsafe names and in reducing medication errors and, therefore, the FDA process replicated externally would be most effective at evaluating proposed trademarks. However, to our knowledge, FDA's current internal review processes have not been independently validated with objective evidence and outcomes metrics, and may not constitute "best practices" compared to other methodologies utilized by industry, academia, and third-party vendors.

BIO encourages the Agency to commission an independent study or establish additional mechanisms under the pilot program to identify which trademark evaluation techniques are most successful at generating quality safety information and ultimately reducing the potential for medication errors.

[i] Institute of Medicine, *Preventing Medication Errors*, July 2006, www.iom.edu/?id=35961
[ii] HHS Advisory Committee on Regulatory Reform, 2002, www.regreform.hhs.gov/finalreport.PDF

DEFINITION OF MEDICATION ERROR:

BIO recognizes that a small percentage of preventable medication errors stem in part from the product name and can be mitigated through enhanced pre-review of the trademark submission. However, BIO notes that sound-alike and look-alike names are only one of many multi-factorial causes of medication errors that can occur along the entire continuum of the health care delivery system. Errors are not only caused by drug names, but also by prescribing errors, communication errors, distribution errors, and a host of other factors. In fact, recent research suggests that only 8% of medication errors are the result of wrong drug errors.[iii] The FDA draft concept paper defines a medication error, as set forth by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), 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 healthcare professional, patient, or consumer" and states that medication use errors occur due to sound-alike or look-alike names, unclear labels, or poorly designed packaging. BIO encourages FDA to incorporate the full NCC MERP medication error definition (below) into the concept paper to ensure that the pilot program seeks to reduce medication errors within the context of the larger health care system.

> "A medication error is 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. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

PILOT PROGRAM SHOULD ENCOURAGE DIVERSE PARTICIPATION:

In order to determine whether the new model for trademark review proposed under the pilot will meet the needs of FDA and the biopharmaceutical industry alike, it will be important that the pilot program encourage diverse and robust participation from both small and large companies, as well as both small-molecule drug companies and large-molecule biotechnology companies. A representative sample of industry in the pilot program – both large and small – will help to determine if the testing requirements are appropriate and not overly burdensome, and whether smaller companies are willing and able to adopt greater responsibility for evaluating proprietary names. BIO would be pleased to work with the Agency to reach out to the biotechnology industry, including members of BIO's Emerging Companies Section, to raise awareness of the pilot program.

[iii] Flynn, Barker, & Carnahan, *National Observational Study of Prescription Dispensing Accuracy and Safety in 50 Pharmacies*, Journal of the American Pharmacists Association, Volume 43, Number 2 / March / April 2003, p. 193.

PROMOTIONAL REVIEW IS OUTSIDE OF THE SCOPE OF THE PILOT:

BIO is fully supportive of the goals of the safety evaluation elements of the pilot program, but believes it is premature and likely inappropriate to transfer the responsibility of promotional evaluation to industry. While progress has been made developing methodologies for safety review, common practices for systematic or qualitative evaluation of a trademark for potential promotional claims or interpretation are less mature and have not been validated. Unless and until such best practices are developed, determining whether claims are "relevant to overstatement of product efficacy, minimization of risk, broadening of product indication, unsubstantiated superiority claims, or names that are overly fanciful" will remain a subjective judgment made by the Agency. Furthermore, this determination is an important FDA compliance activity and it may not be appropriate for industry to conduct this type of evaluation.

BIO suggests that FDA remove the promotional review elements from the pilot program and continue to conduct internal promotional reviews, establish validated practices, and explore emerging methodologies. If the Agency wishes to continue to include promotional review in the pilot, we encourage the Agency to de-link the safety review from the promotional review so that companies can participate in safety review or promotional review without being required to participate in both. We fear that mandatory participation in the promotional review will discourage companies from participating in the pilot program as a whole and may prevent the pilot program from successfully achieving the goals of improving patient safety.

DISPUTE RESOLUTION:

BIO also encourages FDA to establish processes to resolve potential disputes both between FDA and the sponsor, as well as between parallel reviewers that may reach different conclusions on the acceptability of a name.

We recognize that under PDUFA IV, a sponsor can request reconsideration of a rejected trademark by submitting a written rebuttal with supporting data or request a meeting within 60 days to discuss the initial decision. However, there also may be opportunities to enhance the process through informal communication earlier in the review process. For example, when conducting the initial screening for proprietary name submissions against common medical abbreviations, coined abbreviations or the United States Adopted Names (USAN) Council stem list, it would be appropriate to provide the applicants a chance to demonstrate that the names are safe since it will prove difficult to avoid the use of certain common 2 and 3 letter stems in new names.

Additionally, BIO suggests that it would be helpful to have an independent panel of experts available to provide advice if there is a difference of opinion between FDA and the sponsor about the data supported recommendations for trademark acceptability.

EVALUATION OF THE PILOT PROGRAM:

BIO fully expects that external, data driven evaluations of proprietary names, coupled with FDA review of submitted data, will promote consistency for proprietary name review. However, careful evaluation of the pilot program will be necessary to determine if the program should be expanded in 2013. In the absence of reasonable and articulated outcomes measures to determine which process actually meets the goals of the program – reduced medication errors and improved review performance – it will be difficult to determine in a definitive manner which process is superior. We recognize that much of the evaluation will be qualitative, but also encourage the Agency to develop pre-defined metrics and measures to evaluate the pros and cons of both review processes.

We also encourage the Agency to explore whether an objective third party can be used to independently evaluate the pilot program, so that FDA staff would not be placed in the difficult position of evaluating the possible shortcomings of the review processes that they had originally developed.

CONCLUSION:

BIO appreciates this opportunity to comment on the proposed *Pilot Program to Evaluate Proposed Name Submissions*. We believe that this pilot program is an important step forward in establishing consistent practices for evaluating proprietary names to reduce the potential for medication errors and will increase transparency, predictability, and efficiency in the trademark review process. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely,

/S/

Andrew J. Emmett
Director for Science and Regulatory Affairs
Biotechnology Industry Organization