** **Clarification on the Goals of the Pilot Study**

1. It would seem that the main goal of this pilot is to evaluate inter-rater reliability of the concept paper (i.e. given a set of evaluation guidelines, how often do FDA analysts and non-FDA analysts arrive at the same determination regarding the safety of proprietary names). The ultimate goal appears to be "making FDA's application review more efficient and transparent and reducing the likelihood of rejection" (concept paper page 6). Please clarify whether, in fact, FDA is attempting to do more with this pilot, particularly with regard to establishing the effectiveness of the methods outlined in the concept paper for reducing medication errors. Is FDA examining, for example, reductions in medication error as a result of either the concept paper or the pilot study results? If so, how are the evaluations being conducted?

** **Clarification on how Pilot Results will be Evaluated**

2. If inter-rater reliability is the main objective of this pilot, please explain how FDA will evaluate "success" (e.g. a 100% match rate, a 90% match rate, a 50% match rate, etc?). And how does FDA plan to interpret various match rates?
3. Our understanding is that the concept paper is essentially an explanation of the type of analysis FDA undertakes when it evaluates the safety of a proprietary name. If a pilot participant were to follow the methods outlined in the concept paper to the very last detail, and that analysis suggests that the proprietary name is indeed safe, shouldn't the match rate be 100% every time? If not, that would suggest that the results of these various evaluation methods are themselves subject to interpretation. For example, FDA provides an example of how drug companies can conduct name simulation studies and how responses can be coded (table 3 on page 21). Does FDA provide any guidance on how the results of these evaluation methods should be interpreted? For example, how would FDA interpret the results on table 3? Would FDA consider these results to be suggestive of a "safe" name?
4. On page 31 of the concept paper, FDA states that "at the end of the pilot, FDA will evaluate the results to determine if the methods described in this paper are reliable… and if the model of industry conducting reviews, submitting results to FDA, and FDA reviewing the data would be a better model than the current model." Please explain in more precise terms how FDA will establish whether this is a better model. Will FDA be soliciting input from the pilot participants themselves about their experience with implementing the methods in the concept paper and their satisfaction with the overall result?

** **Information Collection Requirements & Burden Estimates**

5. In a number of places in the supporting statement and concept paper, FDA states that more details will be provided about participating in the pilot program *after* OMB approval has been obtained (see, for example, page 3 of the supporting statement). Please explain what other details will be provided to participants that is not already contained in this ICR submission.
6. If a pilot participants proposes to use an alternative method, what form of documentation will the participant need to provide to FDA regarding the methods used and the results of those alternative evaluations? Where is this explained and where is the burden associated with this accounted for?

7. Please explain where the burden and cost estimates come from. Some of the methods in the concept paper would seem to be quite resource intensive (e.g. conducting name simulation studies that would include, as participants, the full range of persons involved in prescribing or administering the drugs, such as physicians, pharmacists, ward clerks, etc.). If a drug company were to implement the methods discussed in the concept paper, what would that typically cost?

** **Questions about Study Design**

8. Please explain in greater detail your approach to participant selection. The supporting statement says that there will be 25-50 submissions as part of this pilot over 2 years, with one or two submissions accepted per month. How will these 1-2 submissions be selected? If the goal is to ensure that there is a good cross-section of applicants (e.g. representing small, medium, large companies), how will such a selection process enable FDA to ensure that the sample is, in fact, representative? What would FDA do if the ultimate sample turns out not to be representative (e.g. if small companies choose not to volunteer for this pilot)?
9. How often is it the case that proprietary drug names are ultimately deemed unacceptable based on information that is not in the public domain (e.g. two drug companies submit proprietary names for FDA review that are similar but the two companies are not aware of each other's submission, or FDA awareness of postmarket experience or error risks to which applicants do not have access, etc.)?

** **Use of the Pilot Study Results**

10. Please explain in greater detail how the results from this study will be used. Once FDA has finished the pilot and held its public meeting, is the immediate next step a guidance document that mandates the use of the methods used in the concept paper? If not, what are the intervening steps?
11. On page 15 of the supporting statement, FDA says that it "is committed to publish draft guidance on best test practices for proprietary name review following public consultation with industry, academia, and others from the general public." By "committed," does that mean FDA is required by statute to do this? Also, we agree that consultation with academics and affected stakeholders is a good idea. Rather than doing this in the form of a public meeting, we would suggest something more systematic (e.g. peer review process, engaging in more formal expert solicitation, etc.).

General or Technical Questions

1. Can FDA clarify the extent to which the methods in the concept paper have been evaluated for their impact on reducing medication errors?
2. What does the following statement mean? "… we note that applicants can participate in the pilot program without submitting any information to evaluate the promotional implications of their proposed proprietary names" (page 10-11 of the supporting statement). What would happen, for example, if pilot participants did not submit any information to evaluate the promotional implications but FDA deemed the proposed name to be unacceptable on the basis of the promotional implications?