Executive Summary
“Decreasing Medication Errors by Minimizing Proprietary Drug Name Confusion”

Protecting public health, promoting patient safety and reducing medication errors are important priorities for FDA and the Office of Drug Safety. FDA has determined that many of the medication errors reported result from proprietary drug names that look or sound like already marketed drug names. We believe that drug-naming mix-ups, along with confusing packaging and labeling of drug products contribute to this public health problem. It is difficult to calculate a firm number of how many medication errors result from proprietary drug name confusion, but we know that a substantial number of medication errors are occurring because of look and sound alike drug name confusion.

The decision to approve a new drug or generic drug ultimately is the responsibility of the Office of New Drugs (OND) or the Office of Generic Drugs (OGD), respectively. OND and OGD consult with other Offices within the Center for Drug Evaluation and Research (CDER) who review proposed drug names for potential risk to patient safety and misleading promotion. The Office of Drug Safety (ODS’s Division of Medication Error Prevention and Technical Support) determines whether the proposed proprietary name(s), because of similarity in spelling or pronunciation, may be confused with the proprietary drug name or the established name of a different drug or ingredient that is already approved. ODS makes this determination based on a review of existing data and generation of additional data through the use of computer analyses, prescription drug name studies and an expert committee.

Recommendation [numsign] 7.3 in the December 1999 Institute of Medicine report “To Err is Human” proposed that FDA require pharmaceutical companies to test (using FDA approved methods) proposed proprietary drug names to identify and resolve potential sound alike and look alike confusion with existing proprietary drug names. In addition, the Office of the Secretary published recommendation [numsign] 238 (from the November 21, 2002, report from the HHS Advisory Committee on Regulatory Reform). This recommendation called for FDA to shift, in most cases, from performing drug name safety testing to reviewing data submitted by sponsors who have followed protocols designed to evaluate their products’ names for possible look-alike and sound-alike errors prior to FDA approval.

Based on these recommendations, FDA, in cooperation with the Institute for Safe Medication Practices and the Pharmaceutical Research and Manufacturers of America, held a public meeting on June 26, 2003 to explore current methods used to evaluate proprietary drug names to reduce medication errors due to similarity in drug names. The June 26th public meeting represented an important effort to discuss testing methods for proprietary drug names in a public forum that included representatives from the pharmaceutical industry, government, academia and health professional organizations and general members of the public.
June 26, 2003 Public Meeting Deliberations

At the public meeting, we discussed proprietary drug naming testing methods including: sampling, questionnaire construction, handwriting and voice recognition modes, use of expert committees and focus groups, computer assisted analyses, use of failure modes and effect analysis and risk management programs. In addition, we opened the floor to the public during an open public hearing. The following questions were presented for comment:

1. Are current methods by sponsors and the FDA appropriate for evaluating look alike and sound alike names? Examples of methods include handwriting and voice recognition studies, computer tools, expert committee analyses and questionnaire/surveys?

2. In studies to evaluate potential medication errors: (a) what is the appropriate study design? (b) What is the appropriate size for an expert committee or for a prescription drug (written and voice recognition) study? (c) What should be the composition of a group of evaluators (e.g., what proportion of physicians, pharmacists, nurses, consumers)? (d) What are appropriate outcome measures?

3. What kind of information (e.g., drug name, strength, quantity, and directions for use) should be included in verbal or handwritten prescription drug studies?

4. Some similar drug names are approved contingent on a pre-marketing agreement for a risk management program. Describe examples of effective risk management programs (e.g., an educational campaign) that could be used to minimize look-alike, sound-alike confusion. How should the effectiveness of the risk management program be evaluated?

5. Should there be different trade-name evaluation procedures for different classes of drugs (prescription vs. over-the-counter)?

FDA reopened the comment period and accepted written comments on this issue until September 6, 2003. Comments submitted to the FDA Docket (No. 02N-0201) as of August 15 are included in this package.

September 19th DSaRM Advisory Committee Discussion
On September 19th, we will continue our discussion from the June 26, 2003 public meeting. We have invited experts to discuss the following methods:

- phonetic/orthographic computer analyses
- expert committees
- focus groups
- simulated practice environment
- field testing
We will ask each speaker to:

- provide a brief overview of the study method
- describe how the study methods should be validated
- propose an optimal design of a study by which applicants could prospectively evaluate the potential for a proposed trade name to lead to medication errors, and
- summarize the strengths and weaknesses of the proposed study design.

**Conclusion**

On September 19th, we will be asking you to consider the advantages and disadvantages of taking a risk-based approach to testing proprietary drug names; identify critical design elements of each method to be included in good naming practices; describe circumstances when a field test should be required and to indicate whether any one method could stand alone; and to describe circumstances, if any, when it would be appropriate to approve a proprietary drug name contingent on a risk management program.