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Dockets Management Branch
Food and Drug Administration, HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0201; BMS ID No0429. Minimizing Medication Errors-Methods for Evaluating Proprietary Names for their Confusion Potential: Public Meeting *(May 30, 2003)*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2002 alone, Bristol-Myers Squibb dedicated $2.2 billion for pharmaceutical research and development activities. The company employs more than 5,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises of approximately 50 compounds under active development.

For these reasons, we are very interested in and well qualified to respond to this FDA request for comments.

We commend the U.S. FDA for its efforts to reduce medication errors, an objective we share. We are pleased to have the opportunity to comment on methods for screening drug names for similarities. Overall we believe that the FDA approach has covered the appropriate domains of screening, and involved the appropriate expertise and interests. Using recent developments in information technology can enhance the methods themselves. Evaluation of the screening process should be conducted to determine if changes are in fact associated with reduced name confusion.

Our specific responses to each item follow.

1. *Appropriateness of methods currently employed by sponsors and FDA to evaluate look-alike and sound-alike names.*

Current methods to evaluate look-alike and sound-alike names vary among sponsors, although most methods involve a combination of prescription testing and expert panel review. It is our impression that FDA methods address appropriate dimensions. Introduction of newer computer-assisted assessment methods such as computational linguistics techniques may result in the reduction of name confusion and consequent medication errors. Calibration of the measurement systems, for example quantifying the frequency of medication errors associated with varying phonological similarity, is necessary to set criteria for acceptable name similarities. Further, criteria such as the maximum tolerable medication error frequencies are necessary in order to evaluate the effectiveness of any medication error prevention efforts.
Moreover, as highlighted in the Public Meeting, it is important in the name evaluation process to weigh appropriately the many factors that can play a role in medication errors. Potential look-alike and sound-alike issues are but two of the myriad of factors. Illegible handwriting when prescribing, distortions in verbal prescribing, and distractions in the prescribing and dispensing settings, are among the other factors that can play a role in medication errors.

2. *Design considerations for studies to evaluate name confusion and potential prescription errors.*

Studies should evaluate each of the written formats (typewritten, handwritten, etc.) in which the prescription is likely to be presented. These formats should be matched to the particular audience of the likely format, e.g., handwritten, typed, computer-generated or verbal prescriptions to pharmacists, or typewritten on a bottle or package for patients.. A combination of observational and quasi-experimental designs can provide good information. In all cases we recommend testing on patients likely to use the medication. The usual considerations of sample size, the variability of measures and appropriate application of statistical tests should be employed.
It is difficult to set the size of expert committees. As a general rule they should be composed of a combination of FDA staff and outside prescriber, dispenser, study design and analysis experts.

3. *Kind of information to include in verbal or handwritten prescription drug studies.*

The drug name should be the primary variable to be examined for the purpose of evaluating proprietary name confusion. Strength, quantity, directions on administration, abbreviations and drug name extents are all additional sources of medication error that could be examined. For studies of handwritten or verbal prescriptions, information on the influence of prescription and dispensing setting, intermediate transcription of orders, language of prescriber and dispenser, and patient characteristics would be of value.

4. *Evaluating the effectiveness of risk management programs in minimizing look-alike, sound-alike confusion.*

Evaluation of such risk management programs for this purpose should have several components and should not be substantially different from the recommendations for evaluation of risk management programs in general. A risk management approach for look-alike, sound-alike confusion should be a last resort option having failed to deal with the potential for confusion at initial name selection and screening. For an education program, prescriber and dispenser knowledge of the education content should be assessed. Prescriber and dispenser performance (frequency of medication error) should also be assessed. Performance can be assessed under research conditions using vignettes. It may be useful to evaluate performance in the prescribing/dispensing setting. This type of evaluation would call for inclusion of patient and systems characteristics.

In addition, prescription and dispensing practices need to be evaluated and improved to reduce medication errors. For example the elimination of oral and handwritten prescribing in favor of electronic prescribing, use of barcoding, use of both generic and brand names in prescriptions, or real-time prescription validation could play an important role in reducing medication errors.

5. *Different trade-name evaluation procedures for different classes of drug (e.g. prescription vs. over the counter).*

The techniques for trade-name evaluation (e.g., studies of orthographical and phonological similarities to established names) may be the same for different classes of drugs. However, the designs of studies, the study subjects, and the important outcomes will vary. For example consumer studies will be important for over-the-counter drugs but perhaps not as important for prescription drugs. Expert committees should have different representation depending on the class of drug being evaluated.

BMS appreciates the opportunity to provide comment and respectfully requests that FDA give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,

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