



November 13, 2003

Dear DSaRM Advisory Committee Members:

It is my pleasure to welcome you to the upcoming Drug Safety and Risk Management Advisory Committee meeting on December 4th. During these deliberations, we will be focusing on ways to reduce the incidence of medication errors due to confusion over names of drugs that look or sound alike. A series of speakers will be discussing a number of proprietary drug name screening methods including:

- Computer analyses (orthographic, phonetic)
- Expert Committees
- Focus Groups
- Simulated Practice Environment
- Field Testing

Many of you participated in the FDA/ISMP/PhRMA public meeting that was held on June 26th in Washington, D.C., that brought together expertise from the pharmaceutical industry, academia, health professionals, government, consumer groups and other interested parties.

On December 4th, we will be seeking your advice in helping us take the next steps by considering the advantages and disadvantages of taking a risk-based approach to testing proprietary drug names. We are looking to identify critical design elements of methods to be included in good naming practices; to describe circumstances when a field test should be required; 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.

The FDA docket did receive comments on this topic in early September. Included are copies of those comments for inclusion as part of the meeting background package you received in preparation for the September 19th meeting.

We appreciate your efforts in this area. Ensuring the safe use of drugs and appropriately managing the risks of medications is pivotal to protecting patients and improving the public health. We are looking forward to continuing to work with you on issues of public health significance relating to drug safety.

Sincerely yours.

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