

August 18, 2003

Dear DSaRM Advisory Committee Members:

It is my pleasure to welcome you to the second day of the two-day (September 18th and 19th) Drug Safety and Risk Management Advisory Committee meeting. During these deliberations, our attention is focused on ways to reduce the incidence of medication errors. On September 19th, you will be hearing from a series of speakers who will elaborate on 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 meeting was a good effort to open this discussion up to appropriate parties, including the pharmaceutical industry, academic experts, health professionals, government representatives, consumer groups and other interested parties.

On September 19th, we will be asking you to take the next step. We will ask 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.

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,

/s/

Victor F.C. Raczkowski, M.D., M.S.

Director

Office of Drug Safety

Enclosures