August 18, 2003

Dear DSaRM Advisory Committee Members:

It is my pleasure to invite you to participate in the FDA advisory committee meetings on September 18 and 19, 2003. Discussions over the next two days will be focused on minimizing the incidence of medication errors.

On September 18, you will be discussing the safe use of drug products packaged in low density polyethylene (LDPE) containers. The current packaging design of LDPE containers is intended to preserve drug product purity. However, current techniques used to label the product (e.g. embossing and debossing) diminish the legibility of the product name and strength. These difficult to read labels and look-alike containers have contributed to medication errors involving the administration of the wrong dosage strength or wrong drug product. We are interested in hearing a discussion about whether there are other solutions or alternative packaging designs that could improve legibility in the label, prevent the ingress of chemical contaminants, but in the process, not lead to additional medication errors. Finally, we would like to hear a discussion about what is the appropriate role for stakeholder input as we continue to resolve this issue.

On September 19, we will be exploring methods to reduce medication errors due to similarities in proprietary drug names in follow up to the FDA public meeting on June 26, 2003.

We are looking forward to seeing you on September 18 and 19 at the Silver Spring Holiday Inn. Thank you for sharing your expertise on these important public health issues relating to risk management and drug safety.

Sincerely yours,

Victor F.C. Raczkowski, M.D., M.S.
Director
Office of Drug Safety