

To: Members, Advisory Committee for Pharmaceutical Science
Manufacturing Subcommittee

From: Helen Winkle
Acting Director, Office of Pharmaceutical Science, CDER, FDA

Date: February 18, 2003

Re: Manufacturing Subcommittee of the Advisory Committee for Pharmaceutical
Science Meeting on March 21, 2003

Dear Manufacturing Subcommittee Members:

I want to start by welcoming you to the first meeting of the Manufacturing Subcommittee. We look forward to your participation on the subcommittee and the value you will add in assisting us in the Office of Pharmaceutical Science (OPS) by providing your scientific input on various important issues in our regulatory processes. There will be a training session on March 11, 2003 to familiarize each of the new members with the CDER (Center for Drug Evaluation and Research) programs and regulatory functions. I hope that each of the new members will be able to attend that training session.

This new subcommittee, which will be chaired by Dr. Judy Boehlert, will focus on a number of topics that relate directly to how we ensure the quality of pharmaceutical manufacturing in both the product review and inspection (GMP – Good Manufacturing Practices) processes. This subcommittee will serve as a forum in the future for vetting a number of issues under the FDA GMP initiative, “Pharmaceutical cGMPs in the 21st Century – a Risk-Based Approach.”

The attached backgrounder packet provides available information on each of the topics to be discussed at the subcommittee meeting on March 21, 2003. The following topics are on the agenda:

- Purpose and mission of the subcommittee
- Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach
- Update - ACPS Process Analytical Technologies (PAT) Subcommittee
- Update - Regulatory approaches regarding aseptic manufacturing
- Subcommittee next steps

Please review backgrounder packet. If you have any questions prior to the meeting, do not hesitate to contact me.

**Advisory Committee for Pharmaceutical Science
Manufacturing Subcommittee
March 21, 2003**

March 21, 2003

Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

FDA/CDER. Pharmaceutical cGMPs for the 21st century: A risk-based approach.

Manufacturing Issues: Sterile Drug Products Produced by Aseptic Processing

FDA/CDER. Sterile drug products produced by aseptic processing draft. Preliminary concept paper. September 23, 2002