

July 2, 2001

Please find the enclosed additional background information for the upcoming July 2001 meeting of the Advisory Committee for Pharmaceutical Science. These materials became available after the first backgrounder was sent.

The additional background information includes:

July 19, 2001

Session: Nonclinical Studies Subcommittee

1. Nonclinical Studies Subcommittee Advisory Committee on Pharmaceutical Science Background Information

Session: Chemistry, Manufacturing and Controls

1. American Association of Pharmaceutical Scientists (AAPS) Workshop - *Streamlining the CMC Regulatory Process NDAs and ANDAs* brochure, June 11-13, 2001
2. Drug Substance Risk Assessment - *Report from Breakout Session*, AAPS Workshop, June 12, 2001
3. Day 2- 9 Product Breakouts, AAPS Workshop, June 11-13, 2001
4. Summary of Comments from Sterile Drug Products and Drug Substances Break Out Sections, AAPS Workshop, June 11, 2001
5. AAPS Workshop on Streamlining the CMC Regulatory Process - *Microbiology Breakout Sessions Summary*, June 13, 2001
6. Risk-based CMC Review, GMP Breakout Sessions Summary, AAPS Workshop, June 11-13, 2001

July 20, 2001

Session: Clinical Pharmacology

1. ACPS (July 20 2001) Questions for Drug Transfer into Breast Milk
2. Advisory Committee of Pharmaceutical Science, Drug Transfer into Breast Milk: Nonclinical and Clinical Methods, July 20, 2001

Session: Complex Drug Substances-Liposome Drug Products

1. Liposomes: Critical Formulation Parameters, AAPS Workshop, June 11-13, 2001
2. Regulatory Science of Liposome Drug Products, Office of Testing and Research, CDER, FDA, June 28, 2001