MEMORANDUM

TO: Members, Advisory Committee for Pharmaceutical Science

FROM: Ajaz S. Hussain, Ph.D.

Deputy Director, Office of Pharmaceutical Science, CDER, FDA

DATE: April 6, 2005

RE: ACPS Meeting May 3-4, 2005

Dear ACPS Members and Invited Guests,

We look forward to meeting with you on May 3-4, 2005, to discuss several important scientific topics. Also, on May 2nd, there will be a one-day training session (not part of the formal ACPS meeting) to be held prior to the full ACPS meeting.

On May 3rd, Ms. Helen Winkle will provide opening remarks and will outline the goals and objectives for this meeting. She will also provide a brief update on Office of Pharmaceutical Science (OPS) activities, to include feedback from the recent PQRI Specifications Workshop.

DAY 1

The first discussion topic will be on a Quality-by-Design (QbD) approach to pharmaceutical quality assurance and control of drug dissolution or release rate characteristics of solid oral drug products. Broadly, this discussion will seek ACPS advice on a regulatory tactical plan for developing a QbD approach to quality assurance of dissolution rate.

Development of regulatory decision criteria based on QbD principles for quality assurance and control of drug dissolution or release rate may serve as a model and could be a milestone in a journey towards the desired state of pharmaceutical quality in the 21st Century. A QbD approach to drug dissolution specification can lead to discussions on more effective and efficient means of managing post approval formulation and manufacturing changes; these principles can then contribute for efficient approaches for establishing therapeutic equivalence of generic drug products.

Day 1 will conclude with a presentation (via phone) by Dr. Jürgen Venitz to update you with a summary report on the November 3-4, 2004, Clinical Pharmacology Subcommittee meeting. The subcommittee met to discuss a number of topics including:

- Pharmacogenics of Irinotecan: Scientific and Clinical Impact of UGT1A1 Polymorphs
- Drug-Drug Interaction Concept Paper: Issues related to CYP, Transporter- and Induction-based Interactions and multiple Inhibitor Drug Interaction Studies
- Transition of Biomarkers to surrogate endpoints: A New Clinical Path Initiative

The briefing information, presentation slides and meeting transcripts are available at the http://www.fda.gov/ohrms/dockets/ac/cder04.html#PharmScience FDA internet website.

DAY 2

Day 2 will begin with a presentation to update you on the current status of the working group on or the Parametric Tolerance Interval Test (PTIT) for Dose Content Uniformity of Aerosol Products. This working group, comprised of a joint FDA-Industry [represented by the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS)], was formed to resolve issues to allow FDA to adopt the use of the PTIT procedure. Dr. Robert O'Neill will present the group's progress report and seek your recommendation on their findings, progress, and planned next steps.

For your reference the information related to the previous ACPS discussions on PTIT (the April and October 2004 meetings) can be located at the following websites:

http://www.fda.gov/ohrms/dockets/ac/04/slides/4034S1_03_O%27Neill.htm
http://www.fda.gov/ohrms/dockets/ac/04/slides/2004-4078S1_03_O%27Neill.htm

For discussion topic #2 we plan to initiate discussions on how pharmaceutical development information may facilitate regulatory decisions on approval of generic drug products. For this initial discussion we will briefly outline our thoughts on three topics:

1. How can pharmaceutical development information help to extend the applications of BCS based waiver of in vivo studies for immediate release products?

2. How can pharmaceutical development information be utilized to address the challenge of highly variable drugs?

3. How can pharmaceutical development information be utilized to support establishing therapeutic equivalence of topical products?

Discussion topic #3 will discuss the issue of “peer review” of laboratory research programs in the OPS. Currently, we have two very different approaches to research management within the Office of Pharmaceutical Science (OPS). We seek ACPS input for developing a common approach and process (e.g., ACPS subcommittee) to periodically evaluate OPS’s laboratory research programs.

We are looking forward to a very stimulating discussion with you on the selected topics. Have a safe and enjoyable journey to Rockville, MD. If you need any additional information please do not hesitate to contact me (hussaina@cder.fda.gov) or Bob King (kingr@cder.fda.gov).