MEMORANDUM

TO: Members, Advisory Committee for Pharmaceutical Science

FROM: Ajaz S. Hussain, Ph.D.
Deputy Director, Office of Pharmaceutical Science, CDER, FDA

Date: 22 September 2003

RE: ACPS Meeting October 21 and 22, 2003

Dear ACPS Members and Invited Guests,

We look forward to meeting you on 21 & 22 October 2003 to discuss several important scientific topics. On October 21 progress reports of the various subcommittees will be presented to you for your assessment and recommendations. Following these reports highlights of the draft PAT guidance (issued on September 3, 2003) presented along with a progress report on the PAT Initiative. Rest of October 21, 2003 will be devoted to discussion on the "Parametric Tolerance Interval for Dose Content Uniformity of Aerosol Products." We had introduced this topic to ACPS as an *awareness topic* at the March 13, 2003 meeting. We have continued to make progress on this, however the progress has been very slow and we wish to seek your input on ways to accelerate progress. In addition to the briefing information included along with this memorandum, information we provided to you for the March 13th meeting is available at http://www.fda.gov/ohrms/dockets/ac/03/briefing/3926b2.htm.

On October 22, 2003 we have selected three topics for discussion. First topic is the "Risk-Based CMC Review" first introduced to the ACPS at the November 2000 meeting (see - http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3657b1a.htm). At this meeting we plan to share with you new proposals on risk based CMC review process within the context of Pharmaceutical cGMP's for the 21st Century Initiative and Quality by Design. In addition to the document describing our current thinking on the topic, two presentations at the recent Manufacturing Subcommittee are provided as background information. This discussion will be followed by a discussion on "drug product nomenclature" and some of the challenges we are facing today. Questions to the committee on this topic are attached. Final topic for discussion will be our proposed strategy and plans for research to support the generic drug program. Some of the challenges we face in assessing the therapeutic equivalence of topical generic products was previous discussed at this meeting (e.g., November 200 meeting on topical skin products. Questions to the committee on this topic are attached. You may wish to review the discussion at the previous meetings (http://www.fda.gov/ohrms/dockets/ac/00/backgrd/3661b1.htm).

We look forward to meeting you on October 21st 2003 and wish you a safe journey to Rockville.