

**ADVISORY COMMITTEE FOR PHARMACEUTICAL SCIENCE**  
**November 15, 2000**

**1 P.M. OPEN PUBLIC SPEAKERS (non-voting) and in order of speaking:**

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| Overview of the ITFG/IPAC-RS Collaboration   | R. Harris Cummings, Ph.D.<br>Executive Director<br>Aerosol Product Development<br>Magellan Laboratories<br>P.O. Box 13341<br>Research Triangle Park, NC 27709<br>Email: RHCUMM@magellanlabs.com |
| BA/BE In Vitro and In Vivo Tests in Draft Guidance   | Lars Borgström , Ph.D.<br>Scientific Adviser<br>Experimental Medicine<br>AstraZeneca R&D Lund<br>S-22187 Lund, Sweden<br>Email: Lars.Borgstrom@AstraZeneca.com                                  |
| Review of BA/BE Team's Responses to BA/BE Questions and Remaining Work   | Lester I. Harrison, Ph.D.<br>Senior Research Specialist<br>3M Pharmaceuticals<br>3M Center, Building 370-3S-05<br>St. Paul, MN 55144<br>Email: liharrison@mmm.com                               |
| Review of CMC Specifications Team's Submissions and Remaining Work (DCU/PSD)                                       | Bo Olsson, Ph.D.<br>Scientific Adviser<br>Microdrug Development AB<br>Sundbyvägen 24<br>645 51 Strägnäs, Sweden<br>Email: <a href="mailto:Bo.Olsson@microdrug.nu">Bo.Olsson@microdrug.nu</a>    |
| Description of Work of the Tests and Methods Team and Forthcoming Submissions                                      | Carole Evans, Ph.D.<br>Section Head<br>Magellan Laboratories<br>P.O. Box 13341<br>Research Triangle Park, NC 277096)<br>Email: cbevan@magellanlabs.com  |
| Description of Work of the Leachables/Extractables Team, Supplier Quality Control Team and Forthcoming Submissions | Gordon Hansen<br>Associate Director<br>Research & Development Center<br>Boehringer Ingelheim<br>900 Ridgebury Road<br>Ridgefield, CT 06877-0368<br>Email: gehansen@rdg.boehringer-ingelheim.co  |
| Concluding Presentation on ITFG/IPAC-RS Collaboration  | Cynthia L. Flynn, Ph.D.<br>Director, Worldwide Drug Product<br>Pharmaceutical Quality Analysis<br>Aventis<br>500 Arcola Road<br>Collegeville, PA 19426<br>Email: Cynthia.Flynn@aventis.com      |

