Advisory Committee for Pharmaceutical Science
March 12 - 13, 2003

Day 1: Wednesday, March 12, 2003

Topical Dermatological Drug Product Nomenclature
Topical dosage from definitions from the CDER Data Standards Manual

Topical dosage form definitions from USP <1151> Pharmaceutical Dosage Forms

Decision Tree

Proposed Definitions for Topical Dosage Forms

Questions to the Advisory Committee

Gupta, P., Garg, S., "Recent Advances in Semisolid Dosage Forms for Dermatological Application", *Pharm. Tech*., March 2002, p. 144-162 (even pages only).

Aulton, M.E. (ed) (2002), *Pharmaceutics: The Science of Dosage Form Design*, 2nd Edition. Formulation of Dermatological Vehicles, p. 528-531

Gennaro, A.R. (ed) (2000), *Remington:The Science and Practice of Pharmacy*, 20th Edition.
Gel and Lotions: p. 745-748
Ointments: p.845-848
Other Medicated Applications: p.856

Lieberman, H.A., Rieger, M.M., Banker, G.S. (eds)(1996*), Pharmaceutical Dosage Forms: Disperse Systems, Volume 2*.
Chapter 5: Topical Suspensions p. 183 – 207
Chapter 10: Gels p. 399-411

Lieberman, H.A., Rieger, M.M., Banker, G.S. (eds)(1988*), Pharmaceutical Dosage Forms: Disperse Systems, Volume 1*.Chapter 6: Pharmaceutical Emulsions p. 199 – 203, p. 217-219, p.232-236

Topical Dermatological Bioequivalence Methods Development

Comparability Protocols
Draft Guidance for Industry: Comparability Protocols - Chemistry, Manufacturing and Controls Information. February 2003.
<http://www.fda.gov/cder/guidance/5427dft.pdf>

Day 2: Thursday, March 13, 2003

Research in OPS
Rapid Response Fact Sheet

Dose Content Uniformity Parametric Tolerance Interval Test for Aerosol Products

Draft Guidance for Industry: Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products - Chemistry, Manufacturing, and Controls Documentation, October 1998. <http://www.fda.gov/cder/guidance/2180dft.pdf>

Guidance for Industry: Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products - Chemistry, Manufacturing, and Controls Documentation, July 2002. <http://www.fda.gov/cder/guidance/4234fnl.pdf>

10. Content Uniformity Test, *The Japanese Pharmacopoeia*, Thirteenth Edition, April 1996, p. 25

Williams, RL , WP Adams, G Poochikian, and WW Hauck. Content Uniformity and Dose Uniformity: Current Approaches, Statistical Analyses, and Presentation of an Alternative Approach, with Special Reference to Oral Inhalation and Nasal Drug Products. *Pharm Res*, 2002; 19:359-66.

Olsson, B. and D Sandell. Delivered Dose Uniformity Testing: IPAC-RS Advocacy and Justification. *Respiratory Drug Delivery VIII Proceedings*, 2002, Vol. I, pp. 115-22.

Hauck, W. An Independent Assessment of IPAC-RS' Proposal. *Respiratory Drug Delivery VIII Proceedings*, 2002, Vol. I, pp. 123-7.

IPAC-RS. A Parametric Tolerance Interval Test for Improved Control of Delivered Dose Uniformity of Orally Inhaled and Nasal Drug Products. 15 November 2001.

Bioequivalence of Endogenous Drugs