

Advisory Committee for Pharmaceutical Science
CDER Advisory Committee Conference Room
5630 Fishers Lane
Rockville, MD

November 28-29 2001

Backgrounder Contents

Agenda

Federal Register Notice

Background Information

Day 1: November 28

Blend Uniformity

Stability Testing and Shelf-life

Process Analytical Technology Subcommittee

Other Subcommittee Reports

Day 2: November 29

Dermatopharmacokinetics

Individual Bioequivalence

Advisory Committee for Pharmaceutical Science Meeting November 28 -29, 2001

Day 1: November 28

Blend Uniformity

CDER Guidance for Industry. ANDAs:Blend uniformity analysis. Draft Guidance, August 1999.

Prescott, James K. and Thomas P. Garcia. A solid dosage and blend content uniformity troubleshooting diagram. Pharm. Tech. March 2001.

Product Quality Research Institute. PQRI blend uniformity data mining exercise: Validation of proposed sampling schema and test criteria. Available from PQRI website <http://www.pqri.org/datamining/index.htm>

Stability Testing and Shelf-life

Process Analytical Technology Subcommittee

Other Subcommittee Reports

Day 2: November 29

Dermatopharmacokinetics

CDER Guidance for Industry. Topical dermatological drug product NDAs and ANDAs - In vivo bioavailability, bioequivalence, in vitro release, and associated studies. Draft Guidance. June 1998.

Franz, Tom. Synopsis - Determination of tretinoin bioequivalence in man by stratum corneum tape stripping. Unpublished.

Pershing, Lynn. Executive Summary - Bioequivalence of three tretinoin gel, 0.025% products. Unpublished.

Gokhale, Mamata. CDER internal dermatopharmacokinetic study. Unpublished.

Individual Bioequivalence

Introduction to the issues.

CDER Guidance for Industry. Bioavailability and bioequivalence studies for orally administered drug products - General considerations. October 2000.

Subject-by-formulation interaction - Examples. Power point presentation.
Undated.

Bioequivalence Criteria Research Program. November 2001.

Chen, Mei-Ling. Data on IBE Studies. Unpublished.

Chen, Mei-Ling and Lawrence J. Lesko. Individual bioequivalence revisited. Clin Pharmacokinet. 40 (10):701-706. 2001

Chen, M. et al. An individual bioequivalence criterion: regulatory considerations. Statistics in Medicine. 19:2821-2842. 2000.

Hauck, W. et al. Subject-by-formulation interaction in bioequivalence: Conceptual and statistical issues. Pharm. Res. 17:375-380. 2000.