Advisory Committee for Pharmaceutical Science Meeting
October 21 - 22, 2003

Bioequivalence of Topical Products
Questions for the Committee:

DPK

What type of studies should be conducted to validate the DPK method?

Q3

What type of data is needed to demonstrate that two products are Q3 equivalent?

How should the Q3 concept be validated or demonstrated?

- Demonstration that we can detect changes in manufacturing processes?
- Demonstration that we can detect formulations with known differences?
- Demonstration that drug release rates are identical?

Bioequivalence for topical products

What role should Q3 and DPK play in the demonstration of bioequivalence for topical products?

- Under what circumstances should Q3 equivalence be sufficient to justify a wavier of in vivo bioequivalence tests?
- Under what circumstances should Q3 equivalence and a DPK method in healthy subjects be sufficient to determine bioequivalence?

Nomenclature
Questions for the Committee:

1. How can the Agency best implement new nomenclature or change existing nomenclature to comply with newer standards?

2. Is it reasonable or useful to include a quantifiable attribute when defining a dosage form or distinguishing between closely related dosage forms where appropriate? Can such an approach be viewed as too arbitrary in some cases and too rigid in other cases?

3. Has the update on topical dosage forms presented today addressed the questions/comments raised by the ACPS at the March 2003 meeting?

4. Is the proposed criterion, i.e., USP disintegration time of less than one minute, reasonable for defining an orally disintegrating tablet?