Dermatopharmacokinetics (DPK)

Background Information

Meeting of the Advisory Committee for Pharmaceutical Science
and the
Dermatologic and Ophthalmic Drugs Advisory Committee

November 17, 2000

Rockville, MD

JOINT ADVISORY COMMITTEE MEETING TO ADDRESS DPK

The purpose of this meeting is to present the historical development of Dermatopharmacokinetics (DPK) as a method of assessing bioequivalence for topical drug products and to give an overview of the current status of the draft guidance. The draft guidance is attached.

Changes that have been made in the guidance since it was last presented to the advisory committees including:

Currently in draft guidance issued in June 1998:

- Applicable to all topical drug products (including vaginal drug products and retinoids)
- Applicable to generic drug products with Q1 and Q2 (+/- 10%)

Changes that will be made based on comments and discussions:

- Not applicable to vaginal drug products
- Applicable to other topical drug products including retinoids
- Applicable to generic drug products with Q1 and Q2 (+/- 5%)

There are still questions regarding the applicability of DPK. These questions will be presented at the meeting along with FDA's strategy for responding to questions/comments. FDA is in the process of conducting additional studies to determine the applicability of the method and to be sure that questions regarding its use are addressed prior to issuance of a final guidance. Ongoing research will be outlined at the meeting.