



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305
Public Health Service

Food and Drug Administration
Rockville MD 20857

2613 '00 JAN 24 A11:06

January 18, 2000

Thomas J. Franz, M.D.
Vice President
Connetics Corporation
Clinical Research-Dermatology
3400 West Bayshore Road
Palo Alto, California 94303

Dear Dr. Franz:

I am writing in response to your letter of October 26, 1999 to Dr. Roger Williams, former Deputy Center Director for Pharmaceutical Sciences, Center for Drug Evaluation and Research (CDER), expressing your support of the Food and Drug Administration's (FDA) proposal to allow manufacturers to substitute skin tape stripping for pharmacodynamic measurements or comparative clinical trials. I apologize for the delay in responding to your letter

Thank you for taking the time to write to the FDA to express your interest and comments on this subject. You can be sure that the Agency will continue to base any decision on sound science.

As you know, on June 18, 1998, the FDA published a Federal Register Notice announcing the availability of a guidance for industry entitled, "Draft Guidance for Industry on Topical Dermatological Drug Product NDA's and ANDA's -- In Vivo Bioavailability, Bioequivalence, In Vitro Release and Associated Studies." This draft guidance is intended to provide recommendations to sponsors of new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements who intend to perform bioavailability and bioequivalence studies for topically applied dermatological drug products during either the pre-approval or post-approval period. The FDA welcomes comments, and I have forwarded a copy of your letter to the Dockets Management Branch for inclusion in the docket (Docket No. 98D-0388).

Thank you for writing. Please do not hesitate to contact us again if you have further questions or comments.

Sincerely,

Theresa M. Martin
Executive Secretariat Staff (HFD-6)
Center for Drug Evaluation and Research

98D-0388

ANS2

Page 2 - Dr. Thomas J. Franz

cc: HFA-305 (w/copy of incoming)
HFD-3/Sherwood

R/D:TMartin:01/18/00 (CDER Log #199911000033)
Concur:KBongiovanni:01/19/00