DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-801

Connetics Corporation
Attention: Sharon L. Hall
Senior Director, Regulatory Affairs
3290 West Bayshore Road
Palo Alto, CA 94303

Dear Ms. Hall:

Please refer to your New Drug Application (NDA) submitted December 22, 2003, under thee Federal Food, Drug, and Cosmetic Act for Evoclin (clindamycin phosphate) Foam, 1%.

We also refer to our approval letter dated October 22, 2004. This application was previously assigned NDA 21-709.

In addition, we refer to the guidance document issued by the Agency in May 1998, *Guidance for Industry and Reviewers Repeal of Section 507 of the Federal Food, Drug, and Cosmetic Act*. This guidance document defines the administrative actions required by the Agency for reviewing and approving antibiotic drug applications that were submitted after November 21, 1997. We also refer to the *Federal Register* notice Docket Number: 99N-3088, *Marketing Exclusivity and Patent Provisions for Certain Antibiotic Drugs* issued January 24, 2000, which lists the active drug substances, including any derivative thereof, that are directly affected by the repeal of Section 507.

The Evoclin (clindamycin phosphate) Foam, 1% application that was previously numbered as NDA 21-709 has been re-numbered to NDA 50-801. All documentation regarding this application should be directed to NDA 50-801 from this date forward.

If you have any questions, call Melinda Harris, Project Manager, at (301) 827-2020.

Sincerely,

{See appended electronic signature page}

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic & Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich
11/9/04 01:42:21 PM
sign off for Dr. Jonathan Wilkin, Division Director