DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021902/S-026

APPROVAL LETTER

Medigene AG
c/o: Medigene, Inc.
Attention: Pam Larson
Associate Director, Regulatory Affairs, US
10650 Scripps Ranch Blvd., Suite 206
San Diego, CA 92131

Dear Ms. Larson:

Please refer to your Supplemental New Drug Application (sNDA) dated October 29, 2012, received November 1, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Veregen® (sinecatechins) Ointment, 15%.

This "Prior Approval" supplemental new drug application proposes the (b) (4) testing panel for the Veregen® botanical starting material and sinecatechins drug substance.

We have completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Matthew White, Regulatory Project Manager, at (301) 796-4997.

Sincerely,

{See appended electronic signature page}

Susan J. Walker, MD, FAAD
Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

SUSAN J WALKER
03/01/2013