DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-902/S-001

MediGene, Inc.
Attention: Pam Larson
Sr. Manager, Regulatory Affairs
10660 Scripps Ranch Blvd., Suite 200
San Diego, California 92131

Dear Ms. Larson:

Please refer to your supplemental new drug application dated December 5, 2006, received December 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Veregen™ (kunecatechins) Ointment, 15%.

This supplemental new drug application provides for incorporation of the newly adopted USAN name of *sinecatechins* to replace the current USAN name of *kunecatechins* on all labels.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA --------/S-001."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submission dated October 26, 2006. The commitment is listed below.

1. A phase 4 study comparing the pharmacokinetics of catechin following topical application of Veregen Ointment, 15%, with that obtained after oral administration of green tea solution. The two-arm study will be designed to enroll into one arm 20 evaluable patients ("completer") with external genital and perianal warts who will be treated 3 times daily for 7 days with Veregen Ointment, 15%, and into the second arm 20 evaluable healthy volunteers, who are to drink a green tea solution 3 times daily for 7 days. Blood samples for the analysis of catechin levels will be obtained prior to and at several sampling time points (over 12 hours) after oral intake of a green teal solution or topical application of Veregen Ointment, 15%, respectively, at Days 1 and 7. The study will be carried out with material from the final commercial source for API to be established in Japan and fulfilling the FDA-defined specifications for the botanical drug substance and drug product.

Protocol to be submitted by July 2007
Study Start Date by January 2008
Final Report Submission by January 2009.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Dermatology and Dental Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Catherine Carr, Regulatory Project Manager, at (301) 796-2311.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
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 Walker
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