DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-756/S-026

Sanofi-Aventis U.S.
Attention: Joanne Robinett
Director, U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Mail Stop: 55A-430A
Bridgewater, NJ 08807

Dear Ms. Robinett:

Please refer to your supplemental new drug application dated September 15, 2006, received September 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BenzaClin® Topical Gel (clindamycin 1%/benzoyl peroxide 5% gel).

We also acknowledge receipt of your submissions dated March 15, April 6, and May 4, 2007.

This supplemental new drug application provides for labeling revisions to the Carcinogenesis, Mutagenesis and Impairment of Fertility section incorporating study findings from your Phase 4 dermal carcinogenicity study. Additionally, this supplemental new drug application provides for labeling revisions to the How Supplied and Compounding Instructions section.

We have completed our review of this application. 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 50-756/S-026."

We have concluded that the following postmarketing commitment from the December 21, 2000, approval letter has been fulfilled.

1. To conduct a dermal carcinogenicity study and a study on the effects on UV-induced skin carcinogenicity. These studies should be completed and submitted within 4 years of the approval of this application.

We remind you of your postmarketing study commitment from the December 21, 2000, approval letter listed below.

2. To conduct a study in patients with acne vulgaris designed to assess the degree of systemic absorption of clindamycin under maximal use conditions (i.e. maximizing the amount applied,

surface area involved, and frequency of application consistent with the approved package insert). Such a study should be done under multiple dosing conditions and include a representative range of ages of both sexes. This *in vivo* pharmacokinetic study should be completed and submitted within 18 months of approval of this application.

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 Margo Owens, Regulatory Project Manager, at (301) 796-2110.

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

Enclosure

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
5/23/2007 05:25:38 PM