DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-756/S-027

sanofi-aventis US
Attention: Joanne Robinett
Director, Regulatory Affairs
55 Corporate Boulevard
Bridgewater, NJ 08807

Dear Ms. Robinett:

Please refer to your supplemental new drug application dated December 20, 2006, received December 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Benzaclin® (Clindamycin 1%, benzoyl peroxide 5%) Gel.

We acknowledge receipt of your submissions dated February 23, April 6, and April 11, 2007.

This "Prior Approval" supplemental new drug application provides for a single phase 6 gram physician sample.

We completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter, for use as recommended in the agreed-upon and attached labeling text.

CONTENT OF LABELING

Within 21 days of the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the submitted labeling (package insert submitted April 11, 2007). The set ID is the unique identifier for the document that remains constant through all versions/revisions of the document. Please assign a different set ID for this labeling to differentiate it from the labeling for the marketed product. For administrative purposes, designate this submission "**Structured Product Labels for approved NDA 50-756/S-027**." Approval of this submission by FDA is not required before the labeling is used.

CARTON LABEL

Please submit the final printed carton and container labels electronically that are identical to the submitted carton and immediate container labels. Alternatively, you may submit 12 paper copies of the final printed carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 6 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 50-756/S-027**." Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available.

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 the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Attachment: Content of Labeling for physician sample

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

/s/

Jim Vidra

4/20/2007 04:03:49 PM