DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50756/-040

SUPPLEMENT APPROVAL

sanofi-aventis U.S. LLC
Attention: Joanne Robinett, Director
55 Corporate Drive
Mail Stop: 55-430A
Bridgewater, NJ 08807

Dear Ms. Robinett:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 2, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BenzaClin® (clindamycin/benzoyl peroxide) Gel, 1%, 5%.

This Prior Approval supplemental new drug application provides for revision to carton and container labels for the currently approved Benzaclin® product line that covers the following package sizes:

1. BenzaClin® Topical Gel 50 gram (pump)
2. BenzaClin® Topical Gel 50 gram (jar)
3. BenzaClin® Topical Gel 25 gram (jar)
4. BenzaClin® Topical Gel 6 gram professional sample

(b) (4)

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may

submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 050756/S-040**." Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Barbara Gould, Chief, Project Management Staff, at (301) 796-4224.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Carton and Container Labeling

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

/s/

BARBARA J GOULD
03/02/2011

STANKA KUKICH
03/02/2011