DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-356/S-007

Merz Pharmaceuticals
Attention: Wendy Jones
4215 Tudor Lane
Greensboro, NC 27410

Dear Ms. Jones:

Please refer to your supplemental new drug application dated March 26, 2007, received March 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Naftin® Gel (naftifine hydrochloride 1%).

This supplemental new drug application provides for changes to add new packaging size, a 90-gram tube, for the commercial drug product. The new size only requires modification to the "How Supplied" section of the package insert with the 90 gram addition.

We 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.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert, and immediate container and carton labels submitted March 26, 2007).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement "NDA 19-356/S-007**". Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this 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
HDF-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 Päivi Miskala, Ph.D., Regulatory Project Manager, at (301) 796-0325.

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Director
Division of Dermatology & 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
9/26/2007 02:04:36 PM