DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-599/S-010

Merz Pharmaceuticals
Attention: Ms. Wendy Jones
Regulatory Affairs Manager
4215 Tudor Lane
Greensboro, NC 27410

Dear Ms. Jones:

Please refer to your supplemental new drug application dated September 25, 2008, received September 26, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Naftin® (naftifine hydrochloride) Cream, 1%.

We acknowledge receipt of your submission dated October 2, 2008.

This supplemental new drug application provides for the addition of a new container /closure system, the **(b) (4)** in 30 gram and 90 gram sizes.

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 and with the minor editorial revisions listed below.

1. The "How Supplied" section was revised to include pumps in 30g and 90g sizes and to reflect the proper storage conditions for the product in the pumps.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert) submitted September 25, 2008.

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 19-599, S-010**." Approval of this submission by FDA is not required before the labeling is used.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Emelia Annum, Regulatory Project Manager, at (301) 796-2223.

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

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

/s/

Stanka Kukich

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