DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-918/S-009

Pfizer Incorporated
Attention: Ms. Dina Russello
Associate Director Regulatory Affairs
Pfizer Consumer Healthcare
170 Tabor Road
Morris Plains, NJ 07950

Dear Ms. Russello:

Please refer to your supplemental new drug application (NDA) dated October 20, 1997, received on October 21, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nix Creme Rinse (1% permethrin shampoo).

We also refer to your amendments dated August 13, 1998, November 17, 1998, April 14, 1999, October 26, 2000 and September 10, 2001. Your submission of September 10, 2001, constituted a complete response to our April 11, 2001, action letter.

This supplemental new drug application provides for Consumer Information Insert Labeling to be included in the product's drug carton, and revised carton and container labels.

We have completed the review of this application, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the FPL submitted on September 10, 2001 (package insert, immediate container and carton labels). As of May 16, 2001, the FPL must also be formatted in accordance with the requirements of 21 CFR 201.66. The product's FPL must be identical to the approved labeling text and in "Drug Facts" format after the compliance date (65 FR 38191 at 65 FR 38193). Failure to comply with these requirements may render the product misbranded and an unapproved new drug.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Tia Frazier, Regulatory Health Project Manager, at (301) 827-2271.

Sincerely,
{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Linda Katz

1/17/02 11:29:15 AM