DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-043/S-006

Bayer Healthcare LLC
Attention: Catherine Fish
Sr. Assoc. Director, Regulatory Affairs
36 Columbia Road
Morristown, NJ 07962-1910

Dear Ms. Fish:

Please refer to your supplemental new drug application dated November 28, 2005, received November 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for RID Mousse (0.33% pyrethrins and 4.0% piperonyl butoxide).

We acknowledge receipt of your submissions dated March 29, 2006, and May 24, 2006.

This supplemental new drug application provides for labeling changes to the carton side panel with information for consumers containing tips to help eliminate lice and to the principle display panel of the carton and can.

We have 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.

The final printed labeling (FPL) must be identical to the submitted labeling (carton and can principle display panel labels submitted on November 28, 2005 and the carton side panel revisions submitted on May 25, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 20-043/S-006**." Approval of this submission by FDA is not required before the labeling is used. This FPL will supersede the previously submitted FPL on September 23, 2005 for S-005.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

In order to retain the "#1 Selling Brand" claim, you must substantiate the claim by submitting UNIT SALES DATA COMPARISIONS for each reporting year to the FDA in your annual report each year.

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office Nonprescription Drug Products
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/

Andrea Segal

5/26/2006 11:25:05 AM