CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-043

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 21-043

Soltec Research USA
Attention: Thomas Blake, R.Ph.
Regulatory Consultant to Soltec
48 Mount Olive Road
Budd Lake, New Jersey 07828

MAR 7 2000

Dear Mr. Blake:

Please refer to your new drug application (NDA) dated August 31, 1998, received September 9, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 330.11 for RID Mousse [pyrethrum extract (equivalent to 0.33% pyrethrins), and 4% piperonyl butoxide] aerosolized foam. This new drug application deviates from the monograph for OTC pediculicide drug products (21 CFR 358 Subpart G) in that the product is an aerosolized foam.

Please also refer to your approvable letter dated July 8, 1999.

We acknowledge receipt of your communications dated July 16 and 29, September 2 and 8, and November 1 and 10, 1999; and January 27 and 31, February 14, and March 1, 3, 4, and 7, 2000. Your submission of September 2, 1999, constituted a complete response to our July 8, 1999 approvable letter.

This new drug application provides for the use of RID Mousse [pyrethrum extract (equivalent to 0.33% pyrethrins), and 4% piperonyl butoxide] aerosolized foam for the treatment of head, pubic (crab), and body lice.

We have completed the review of this application, as amended, and have concluded that the product meets all of the conditions of the applicable monograph and is approved for the deviation included in this new drug application. The product is safe and effective for use as recommended in the draft labeling dated February 14, 2000 [carton label and immediate container (can) label] and January 31, 2000 [consumer information insert]. Accordingly, the application is approved effective on the date of this letter.

As you agreed in your letters dated March 4 and 7, 2000, please be reminded that you are responsible for the following:

1. The translation of the Spanish Consumer Information Insert will be identical to the approved English version of the Consumer Information Insert; and

2. The word "new" will be deleted 6 months after initial marketing from the carton, immediate container, and any other labeling for this product.

3. Under the "Active Ingredients (calculated without propellant) Purpose", the "L" in "Lice treatment" should be in upper-case.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-043." Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, further revision of the labeling may be required.

As of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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 regarding this application, please call Thomas Parmelee, Pharm.D., Regulatory Project Manager, at (301) 827-2271.

Sincerely,

/S/

Charles Ganley, M.D. 3/7/00
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research