



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAY - 6 1998

Ronald Bynum
Manager, Regulatory Affairs
Alpharma U.S. Pharmaceutical Division, Inc.
Research & Development Center
The Johns Hopkins Bayview Center
333 Cassell Drive, Suite 3500
Baltimore, MD 21224

RE: **ANDA# 74-806**
Acticin™ (permethrin) Cream, 5%
MACMIS ID # 6606

Dear Mr. Bynum:

Reference is made to Alpharma U.S. Pharmaceutical Division, Inc.'s (Alpharma) promotional materials for Acticin™ (permethrin) Cream, 5%, which include:

These materials were submitted to the Division of Drug Marketing, Advertising and Communications (DDMAC) by Alpharma in draft form on March 16, 1998, with a request for comments. DDMAC provided comments on the contents of the above promotional materials in a letter to Alpharma dated April 6, 1998, indicating that certain claims and representations in the materials would be false or misleading. Although Alpharma had requested comments, on April 14, 1998, Alpharma acknowledged that they had disseminated the promotional materials prior to receipt of DDMAC's letter.

DDMAC finds that they contain false and/or misleading claims in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

- The materials are misleading because they make comparative claims, for example, suggesting that "Acticin is less viscous than Elimite, making it easy to apply," without substantial evidence. In addition, the claim that "Patients should find it easy to apply--even in the skin creases and crevices where scabies mites live," in juxtaposition with this comparative claim implies, without substantial evidence, that because it is easier to apply in difficult skin creases and crevices where scabies mites are found, it may be more effective than Elimite. Furthermore, lower viscosity does not necessarily correlate with "Better Spread," as the headline suggests.
- The promotional materials are misleading because they lack fair balance. For example, they fail to mention precautions such as the possibility that treatment with permethrin cream may temporarily exacerbate conditions, such as pruritis, edema, and erythema associated with scabies infestation. In addition, they fail to mention that "In clinical trials, generally mild and transient burning and stinging followed application with permethrin cream in 10% of the patients and was associated with the severity of the infestation. Pruritis was reported in 7% of patients at various times post-application."
- The claims, for example, "Less expensive," "Acticin costs less than Elimite," "Significant savings compared to Elimite," and "Acticin costs less than Elimite" are misleading because they make comparative cost savings claims without adequate support.

DDMAC acknowledges Alpharma's statements, in its letter dated April 21, 1998, that it has ceased dissemination of the aforementioned materials, and will attempt to destroy any copies in its, or its marketing partners', possession. We also acknowledge Alpharma's stated intention to revise future promotional materials to correct these violations. DDMAC considers Alpharma's actions to be sufficient to address the violations, and therefore considers this matter closed.

If Alpharma has any questions or comments, please contact me by facsimile (301) 594-6771, or by written communication at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, 5600 Fishers Lane, HFD-40, Rm. 17B-20, Rockville, MD 20857.

Ronald Bynum
Alpharma U.S. Pharmaceutical Division, Inc.
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In all future correspondence regarding this matter, please refer to the MACMIS ID 6606, in addition to the NDA number.

Sincerely yours,

Jean E. Raymond, P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications
