DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NOV 15 2000

TRANSMITTED VIA FACSIMILE

Ms. Roma Plakyda
Regulatory Services Specialist
Bristol-Myers Squibb Company
P.O. Box 4500
Princeton, NJ 08543-4500

Re: NDA 21-145
Vaniqa (eflornithine hydrochloride) Cream, 13.9%
MACMIS ID# 9515

Dear Ms. Plakyda:

As part of our routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a direct-to-consumer (DTC) broadcast television advertisement (A2K011) for Vaniqa (eflornithine hydrochloride) Cream, 13.9% disseminated by Bristol-Myers Squibb Company (BMS). DDMAC has concluded that the broadcast advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations for the following reasons:

Your broadcast advertisement is misleading because it minimizes important contextual information regarding Vaniqa through the use of small type size and ambiguous language. The advertisement briefly displays a SUPER in small sized type that states, "Works with current hair removal methods." This language inadequately communicates the concept discussed in the approved patient labeling about the necessity of continued use of the patient's current hair removal techniques while using Vaniqa.

Furthermore, your broadcast advertisement does not fulfill the requirements for adequate provision of the approved product labeling. The presentation of the 1-888 phone number and the website SUPERS, combined with other text presented in the same frame, lacks sufficient prominence, spacing, and contrast to be legible and understandable by the viewer. This issue was discussed with BMS in our September 27, 2000, comment letter.

Action Requested

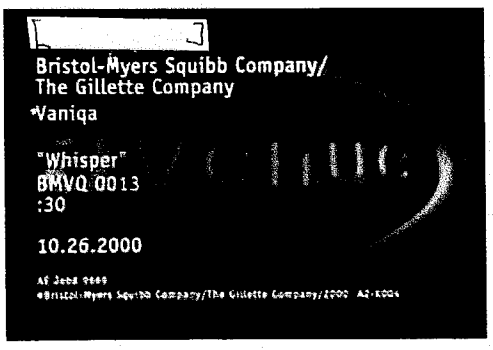
You should immediately cease the airing of this television broadcast advertisement and the use of all other promotional materials for Vaniqa that contain the same or similar presentations cited in this letter. You should submit a written response, on or before November 30, 2000, describing your intent and plans to comply with the above. Your letter should include a list of all promotional materials that were discontinued, and the discontinuation dates.

You should direct your response to me by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17 B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind you that only written communications are considered official. In all correspondence regarding this particular submission, please refer to MACMIS ID# 9515 in addition to the NDA number.

Sincerely,

/S/

Cheryl Y. Roberts, MS, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications



VANIQA.

VANIQA.

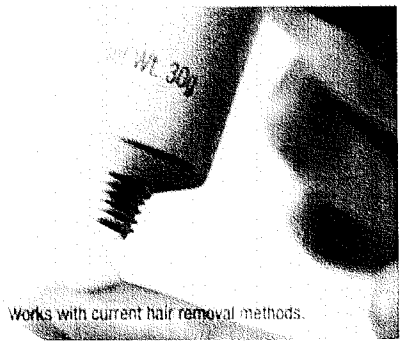
WOULD YOU DARE

LET SOMEONE GET THIS CLOSE?

NOW IT'S POSSIBLE.

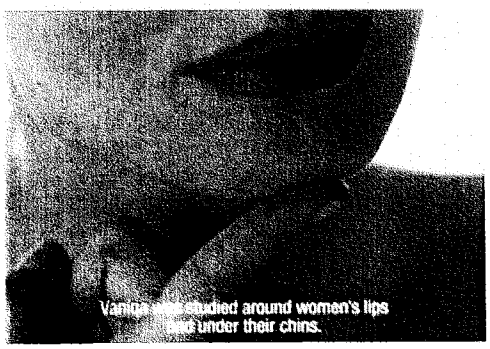
VANIQA

VANIQA. IT'S NOT A HAIR REMOVER.



IT'S THE FIRST PRESCRIPTION CREAM

THAT SLOWS THE GROWTH



OF UNWANTED FACIAL HAIR IN WOMEN.

SOME MAY EXPERIENCE MILD TINGLING,

BURNING, STINGING OR RASH.

VANIQA

ASK YOUR DOCTOR ABOUT VANIQA.

NOW, UP CLOSE IS UP TO YOU.

A2-K011