NDA 21-145

Westwood-Squibb Colton Holdings Partnership
Bristol-Myers Squibb
Attention: Kathy B. Schrode, Ph.D.
Group Director
Life Style Enhancement
Regulatory Sciences
Route 206
Princeton, New Jersey 08543-4000

Dear Dr. Schrode:

Please refer to your new drug application (NDA) dated September 24, 1999, received September 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vaniqa (eflornithine hydrochlorine) Cream, 13.9%.

We acknowledge receipt of your submissions dated October 15, 1999, January 12 and 24 (2), March 2 and 28 (2), April 24, May 1, 3, 19 and 24, June 5, July 6, 11 (3), 17, 20, 21, 24 (2), 26 (2) and July 27 (3), 2000.

This new drug application provides for the use of Vaniqa (eflornithine hydrochlorine) Cream, 13.9%, for the reduction of unwanted facial hair in women.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 27, 2000, patient package insert submitted July 27, 2000, immediate container and carton labels submitted July 21, 2000**).** We remind you of your July 24, 2000, commitment, made during labeling negotiations, to revise the description of the inactive ingredients on the cartons and container labels to coincide with the package insert at the next printing**.** Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-145." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitments specified in your submission dated July 27, 2000. The commitment, along with completion date agreed upon, are listed below.

Phase 4 COMMITMENT

The Applicant agrees to add a test for [ ] of the product to the stability storage testing program. Data will be collected for the first three commercial lots over the approved shelf-life (24 months). The collected data for these three lots will be analyzed and submitted to the Agency for review within four months of completion of the 24 month stability study for the third lot. If the data indicate a [ ], a [ ] would then be required.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitment, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.81(b)(2)(vii), we request that you include a status summary of the commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to the Phase 4 commitment must be clearly designated "Phase 4 Commitments."

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, 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 pediatric studies in the pediatric population below the age of 12 years, because there are sufficient data to determine efficacy and safety down to and including age 12 years. In the below age 12 year group, the necessary studies are impossible or highly impractical to conduct because the number of patients is too small.

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-42
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, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research