DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-732

Valera Pharmaceuticals, Inc.
Attention: William B. Gray, M.S.
Senior Director, Regulatory Affairs
8 Clarke Drive
Cranbury, NJ 08512-3617

Dear Mr. Gray:

Please refer to your new drug application (NDA) dated December 12, 2003, received December 12, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for VANTAS™ (histrelin implant).

We acknowledge receipt of your submissions dated December 23, 2003; February 2 and 20; March 25; April 9, 13, and 30; June 2, 3, 21, 24, and 30; July 1, 22, and 27; August 6, 9, 18, 19, and 30; September 1, 3, 7, 8, 9, 16, 17, 22, 23, 29, and 30; October 1, 5, 6, 7, and 8, 2004.

This new drug application provides for the use of VANTAS™ (histrelin implant) for the palliative treatment of advanced prostate cancer.

We completed our review of this application and it 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 enclosed labeling (package insert submitted October 7, 2004, patient package insert submitted October 7, 2004, immediate container and carton labels submitted October 8, 2004. Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved new drug.

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 NDA 21-732**." Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment in your submissions dated September 30, and October 1, 2004, as stated below:

> Conduct a study investigating 10 patients with difficult to locate or non-palpable implants. The study will collect information on these patients utilizing the instructions in the physician label, including specialized investigations such as ultrasound and CT scan, to aid in the location and removal of the implant. The data from the study will be provided as a report to the Agency.
>
> Protocol Submission: by December 15, 2004
> Study Start: by January 31, 2005
> Final Report Submission: by October 31, 2006

Submit clinical protocols to your IND for this product. We encourage you to submit your study protocol to the Division of Reproductive and Urologic Drug Products for review and comment prior to the initiation of your postmarketing studies. Submit nonclinical protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of your commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Reproductive and Urologic Drug Products and two copies of both the promotional materials and labeling directly to:

> Division of Drug Marketing, Advertising,
> and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

If you have any questions, please call Nenita Crisostomo, R.N., Regulatory Health Project Manager, at (301) 827-7260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames
10/12/04 09:31:13 AM