DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-402/S-041

JHP Pharmaceuticals, LLC
Attention: Stuart Hinchen
President
19 Fox Hedge Road
Saddle River, NJ 07458

Dear Mr. Hinchen

Please refer to your supplemental new drug application dated June 8, 2007, received June 11, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Delestrogen (Estradiol Valerate Injection, USP).

We acknowledge receipt of your submissions dated September 13 and 21, 2007.

This supplemental new drug application provides for adding an additional manufacturing, packaging, and testing facility for the drug product; a new analytical method for determining the API and impurities in the drug product; and a revised stability protocol.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on June 8, 2007.

Please be advised that "Rx Only" is not required for the Content of Labeling and should either be deleted or moved to the Title section of the package insert (See section IV. 3. in the Guidance for Industry: Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 – Elimination of Certain Labeling Requirements). This change can be made and reported in the next annual report.

We acknowledge your June 8, 2007, submission containing final printed carton and container labels.

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 9-402/S-041**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Hasmukh Patel

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