DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-248/S-034

Abraxis Pharmaceutical Products
Attention: John M. McNally
Regulatory Scientist
Riverway One
6133 N. River Road, Suite 500
Rosemont, IL 60018

Dear Mr. McNally:

Please refer to your supplemental new drug application dated November 3, 2006, received November 7, 2006, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxytocin Injection, USP.

We acknowledge receipt of your submissions dated February 19, March 1, 5, and 28, 2007. Your submission of March 28, 2007 constituted a complete response to our March 7, 2007, action letter.

This supplemental new drug application provides for the following:

- Creation of one new 10 USP Units/mL drug product code, 30 mL fill in a 30 mL vial
- One additional facility to perform release and stability testing of the drug substance and drug product
- Changes to labeling resulting from the additional package configuration

We completed our review of this application, as amended. This application 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 submitted labeling (package insert submitted March 5, 2007, immediate container and carton labels submitted November 3, 2006).

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 supplement NDA 18-248/S-034**." Approval of this submission by FDA is not required before the labeling is used.

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:

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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

7/27/2007 12:33:03 PM