



NDA 18-261/S-028

Parkedale Pharmaceuticals Inc. (a wholly owned subsidiary of King Pharmaceuticals, Inc.)
Attention: Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated March 27, 2007, received March 28, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pitocin[®] (Oxytocin Injection, USP) 10 Units/mL.

We acknowledge receipt of your submissions dated June 5 and July 20, 2007.

This supplemental new drug application provides for a change in the stopper and storage temperature from the currently approved 2 °C – 8 °C to 15 °C – 25 °C for 1 mL and 10 mL vials.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the attached labeling (package insert submitted March 27, 2007). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 18-261/S-028"

CARTON AND IMMEDIATE 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 18-261/S-028.**” 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 safety 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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