DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-261/S 023

King Pharmaceuticals, Inc.
Attention: Mr. Tom W. Der
Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Der:

Please refer to your supplemental new drug application dated June 21, 2002, received June 24, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pitocin® (oxytocin injection) USP Synthetic.

We acknowledge receipt of your submission dated September 6, 2002.

This supplemental new drug application provides for holding the drug product for 30 days at room temperature and revision of the labeling (package insert and carton labels) to reflect this holding period.

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, submitted September 6, 2002, and with the minor editorial revisions listed below.

Add degrees Fahrenheit indicated in parentheses to the new temperature data for clarity and continuity as follows:

> Store at 2°-8°C (36°-46°F). May be held at 15°-25°C (59°-77°F) for up to 30 days. Discard after holding at 15°-25°C (59°-77°F).

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the package insert and carton labels submitted September 6, 2002. These revisions are terms of the approval of this application.

Please submit the FPL electronically 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, 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-261/S-023. 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:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Karen Anderson, N.P., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Deputy Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
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/

Donna Griebel

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