# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number: NDA 18261/S11**

## APPROVAL LETTER

NDA 18-261/S-011

JUL 29 1997

Parke-Davis Pharmaceutical Research
Attention: Mr. James A. Parker, Jr.
Director, Worldwide Regulatory Affairs
201 Tabor Road
Morris Plains, NJ 07950

Dear Mr. Parker:

Please refer to your supplemental new drug application dated July 10, 1996, received July 11, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and the provisions of 21 CFR 314.70 (c) for Pitocin (oxytocin injection).

The supplemental application provides for the deletion of all references to the 0.5 mL ampule, which is no longer marketed and the revision of the **PRECAUTIONS** and **ADVERSE REACTION** sections in which the word is replaced with the word

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on July 10, 1996. Accordingly, the supplemental application is approved.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, 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 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Christina Kish, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

/S/

7-28-97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Orig. NDA
HFD-580
HFD-580/HJolson/PPrice/LRarick
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFD-735/DPE (with labeling)
HFI-20/Press Office (with labeling)
HFD-580/CKish/7.23.97/n18261ap.s11
concurrence: Lpauls 7.23.97/PPrice 7.24.97/HJolson 7.25.97

SUPPLEMENT APPROVAL (S/AP)

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 18261/S11

## MEDICAL REVIEW(S)

ORIGINAL

Medical Officer's Summary of NDA Supplement

NDA 18-261/S011

JUL 23 1997

Name of Drug: Pitocin (Oxytocin injection)

Sponsor: Parke-Davis

Material Reviewed: Labeling supplement

Date of Correspondence: July 11, 1997

Comments:
This labeling has previously been reviewed by the CSO, Christina Kish, and changes made to the PI have been noted by her. Proposed changes to the sponsor's label are:

Recommendation:
Changes to FPL are acceptable.

/S/

Phill H. Price, M.D.
7/21/97

Concur 7/23/97

# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 18261/S11

## CORRESPONDENCE

201 Tabor Road
Morris Plains, NJ
07950
Phone: 201-540-2000

NDA NO. 18261 REF. NO. 011

NDA SUPPL FOR 5/12

ORIGINAL

NDA SUPPLEMENT

PARKE-DAVIS
People Who Care

July 10, 1996

NDA 18-261
Pitocin® (oxytocin injection, USP) Synthetic

AJ 8/6/97

Re: Special Supplement - Changes Being Effected

initial mailed 8/4/97

Solomon Sobel, M.D.
Director
Division of Metabolism and Endocrine Drug Products
HFD-510
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUL 11 1996
HFD-510

Dear Dr. Sobel:

Reference is made to our approved NDA for Pitocin® (Oxytocin Injection, USP) Synthetic.

In accordance with 21 CFR §314.70 (c)(2)(iii), we are revising the DOSAGE AND ADMINISTRATION section of the Pitocin package insert to delete reference to the 0.5 mL ampoule which is no longer marketed. Specifically, in the subsection "A. Induction or Stimulation of Labor" under "1. Preparation" we have deleted the last sentence which read:

Since the 0.5 mL ampoule product is no longer available, we believe this revision strengthens the information about dosage and administration that is intended to increase the safe use of this product.

In addition, we have revised the PRECAUTIONS and ADVERSE REACTIONS sections to comply with 21 CFR §201.57 (f)(9), "Pediatric Use". Specifically, under PRECAUTIONS, subsection Pregnancy, Nonteratogenic Effects, we have deleted the word from the first sentence and replaced it with The revised sentence now reads:

This revision more accurately reflects the pediatric population which may be affected by the use of Pitocin, since infant was defined in FDA's final rule as 1 month to 2 years in age versus neonate which was defined as birth to one month. We would not expect Pitocin to be used in infants.

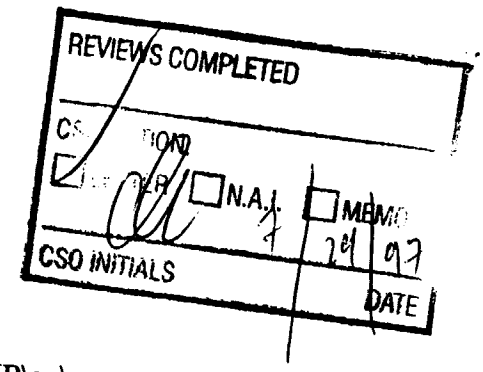
A similar revision was made in the ADVERSE REACTIONS section, fifth paragraph, first line. The revised sentence now reads:

Included herein as Attachment 1-3 are twelve final printed copies of the revised Pitocin package inserts. Please be advised there are three package inserts that are used in the packaging of Pitocin. They each contain identical text and differ only in physical size and/or the location of identity codes. The following are attached:

| Attachment | Specification Number | Revision Date |
|---|---|---|
| 1 | | June 1996 |
| 2 | | June 1996 |
| 3 | | June 1996 |

In addition, we have included in Attachments 4-6 respectively, a copy of each package insert showing the revisions that are being made. These revisions are being implemented immediately.

If you have any questions or require additional information, please do not hesitate to contact me at 201/540-3113 or FAX 201/540-5972.




Sincerely,

James A. Parker, Jr.
Director
Advertising and Labeling
Worldwide Regulatory Affairs

JP\sv\rm
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Attachments