



NDA 18-261/S-021

Parkedale Pharmaceuticals, Inc.  
Attention: Greg Carrier  
Regulatory Affairs  
501 Fifth Street  
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated May 17, 2001, received May 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pitocin® (oxytocin injection USP).

This supplemental new drug application provides for the omission of the Geriatric Use subsection in the labeling of this product.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and patient package insert submitted May 17, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is 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 20857

Please submit one market package of the drug product when it is available.

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, call Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

*{See appended electronic signature page}*

Daniel Shames, M.D.  
Acting Director  
Division of Reproductive and Urologic Drug Products  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

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/s/

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Daniel A. Shames  
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