DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-530/S-024

JHP Pharmaceuticals, LLC
Attention: Carla English
Sr. Regulatory Affairs Associate
Morris Corporate Center 2
One Upper Pond Road
Building D, 3rd Floor
Parsippany, NJ 07054

Dear Ms. English:

Please refer to your supplemental new drug application dated September 21, 2007, received September 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tigan (trimethobenzamide hydrochloride) 100 mg/mL Intramuscular Injection.

We acknowledge receipt of your submissions dated February 1, 2008 and March 26, 2008.

This supplemental new drug application provides for the creation of a stand alone package insert for Tigan® Injection, inclusion of a "Geriatric use" subsection, and additional cautionary statements in the labeling regarding its use in elderly patients (who often have impaired renal function) as well as patients with renal disease.

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.

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 enclosed labeling (text for the package insert). These revisions are terms of the approval of this application. 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 supplement NDA 17-530/S-024**."

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted labeling (package insert submitted March 26, 2008).

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 17-530/S-024**." 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
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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert Label

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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