DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-194/S-068

Hospira, Inc.
275 North Field Drive
Bldg. 2-J45-2
Lake Forest, IL 60045-5046

Attention: Anne E. Bailey
Senior Specialist, Global Regulatory Affairs

Dear Ms. Bailey:

Please refer to your supplemental new drug application dated March 7, 2003, received March 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Talwin® (pentazocine Lactate Injection, USP).

We acknowledge receipt of your submissions dated July 23, 2003, and January 26, March 29, April 1, April 7, April 15, and May 18, 2004.

Your submission of January 26, 2004, constituted a complete response to our July 10, 2003, action letter.

This supplemental new drug application provides for (b)(4)----------the active pharmaceutical ingredient (API), pentazocine USP, revisions to the drug product specifications, and a reduction in the expiration dating period for the drug product.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter.

We remind you of your postmarketing study commitment in your submission dated May 18, 2004. This commitment is listed below.

1. Provide within nine months from the date of this letter, the results of two in-vitro genotoxicity studies, namely, a point mutation assay and a chromosomal aberration assay, in support of the qualification of morphane in the drug product.

   Final Report Submission: by March 1, 2005

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected

summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

Due to the current drug shortage situation, the drug product batches manufactured using pentazocine (b)(4)----------may be released for marketing. We remind you of your ----------y 14, 2004, to use pentazocine containing pentazocine-(b)(4)----------for the production of all future Talwin batches.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Lisa Basham-Cruz, Regulatory Project Manager, at (301) 827-7420.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

5/27/04 06:40:29 PM