DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-108/S-026

JHP Pharmaceuticals, LLC
Attention: Carla English
Senior 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 March 28, 2007, received March 29, 2007, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coly-Mycin® M Parenteral (colistimethate for Injection, USP).

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This "Changes Being Effected" supplemental new drug application provides for revisions to **WARNINGS** section, and **PRECAUTIONS** section, **Information for Patients** subsection of the package insert to add information regarding *Clostridium difficile* associated disease (CDAD) as requested by the Agency in the letter dated September 29, 2006.

We completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 28, 2007.

We request, however, at the next printing that the word colistemethate that appears in the first sentence of the **PRECAUTIONS** section, **Geriatric Use** subsection, be corrected to read colistimethate.

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
5600 Fishers Lane, Suite 12B05
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 Maureen Dillon-Parker, Chief, Project Management Staff, at (301) 796-0706.

Sincerely,

{See appended electronic signature page}

Wiley Chambers, MD
Acting Director
Division of Anti-Infective and
Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure – Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers

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