DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-356/S-050

JHP Pharmaceuticals
Attention: Carla English
Senior Regulatory Affairs Associate
Morris Corp. Center 2
1 Upper Pond Road
Bldg. D, 3rd Floor
Parsippany, NJ 07054

Dear Ms. English:

Please refer to your supplemental new drug application (sNDA) dated November 12, 2003, received November 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coly-Mycin® S Otic (colistin sulfate-neomycin sulfate-thonzonium bromide-hydrocortisone acetate otic suspension).

We acknowledge receipt of submissions dated May 2 and July 7, 2007, and May 12, 2009. Your submission dated May 2, 2007, constituted a complete response to our May 6, 2004 action letter.

This supplemental new drug application provides for a Geriatric Use subsection in the label.

We completed our review of this application as amended, and it 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 submitted on May 12, 2009). 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 NDA 50-356/S-050."

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
Suite 12B05
5600 Fishers Lane
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 Susmita Samanta, MD, Regulatory Project Manager, at 301-796-0803.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

6/2/2009 04:52:28 PM