DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-606/S-026 **SUPPLEMENT APPROVAL**

ViroPharma Incorporated
Attention: Pansy L. Jordan, MBA
Assistant Director, Regulatory Affairs
397 Eagleview Boulevard
Exton, PA 19341

Dear Ms. Jordan:

Please refer to your supplemental new drug application dated May 16, 2008, received May 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancocin® HCL (vancomycin hydrochloride capsules, USP), 125 and 250 mg.

This "Changes Being Effected" supplemental new drug application provides for changes to the carton for the drug product, including the following:

- Removal of HCL from the tradename
- Redesign of artwork and color scheme
- Website name updated to www.Vancocin.com
- Replaced part numbers:
  - OSG00670 (125 mg capsule carton) with PKG00770
  - OSG00671 (250 mg capsule carton) with PKG00771

We have completed our review of this application and it is approved, effective on the date of this letter. Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and/or submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).*

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Carton and Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-50606	SUPPL-26	VIROPHARMA INC	VANCOCIN HYDROCHLORIDE PULVULES

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

/s/

KATHERINE A LAESSIG
01/08/2010