



NDA 21-511/S-012

Hoffman-La Roche  
340 Kingsland Street  
Nutley, New Jersey 07110-1199

Dear Ms. Dowling:

Please refer to your supplemental new drug application dated May 20, 2005, received May 24, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Copegus® (ribavirin) 200 mg tablets.

We acknowledge receipt of your submission dated November 22, 2005.

This supplemental new drug application provides for revisions to the Package Insert to add information to the Clinical Pharmacology section regarding the pharmacokinetic results from Clinical Study Report NP17354.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for package insert and text for the patient package insert).

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 21-511/SN-012.**" 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  
WO 22, Room 4447  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

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 Kenny Shade, Regulatory Project Manager, at (301) 796-0807 or (301)796-1500.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure:

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

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Debra Birnkrant  
11/23/2005 12:43:26 PM  
NDA 21-511