Dear Mrs. Percival:


These “Changes Being Effected” supplemental new drug applications provides for:

- S008- Changes to the US package insert ADVERSE REACTIONS section, which include updating post-marketing safety information.

- S011- Changes to the US package insert CLINICAL PHARMACOLOGY: Microbiology section, as requested in FDA communication dated May 19, 2006.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

Sincerely,

[See appended electronic signature page]

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure (Approved Labeling)
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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Jeffrey Murray
8/9/2006 12:10:23 PM