DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-649/S-012
NDA 19-650/S-009

Forest Laboratories, Inc
Attention: Edward Lee
Assistant Director, Regulatory Affairs
Harborside Financial Center III
Suite 602
Jersey City, NJ 07311

Dear Mr. Lee:

Please refer to your supplemental new drug application dated July 2, 2007, received July 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flumadine® (rimantadine) tablets and syrup.

These "Changes Being Effected" supplemental new drug applications provide for:

- Inclusion of information to the PRECAUTIONS section regarding potential rimantadine drug interaction with Live Attenuated Influenza Vaccine (LAIV)

We completed our review of these supplemental new drug applications, as amended. These are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 2, 2007.

If you have any questions, call Jaewon Hong, Regulatory Project Manager, at (301) 796-2013.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Debra Birnkrant
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NDA 19-650, 19-649