DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-649/S-010
NDA 19-650/S-007

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 August 28, 2006, received August 29, 2006, 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 application 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 applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

- The Agency requests for next printing of labels for the sponsor to replace all reference to Flumist® trade name with the generic name, Live Attenuated Influenza Vaccine (LAIV)

The concurrent use of Flumadine® with live attenuated intranasal influenza vaccine has not been evaluated. However, because of potential interference between these products, the live attenuated intranasal influenza vaccine should not be administered until 48 hours after cessation of Flumadine® and Flumadine® should not be administered until two weeks after the administration of live attenuated intranasal influenza vaccine unless medically indicated. The concern about potential interference arises principally from the potential for antiviral drugs to inhibit replication of live vaccine virus.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated. These revisions are terms of the approval of these applications.

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

Enclosure
Package Insert (PI) dated August 28, 2006 (NDA 19-649 SLR-010/NDA 19-650 SLR-007)

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

/s/

Jeffrey Murray
3/14/2007 04:10:44 PM