DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-649/SLR-006
NDA 19-650/SLR-004

Forest Laboratories, Inc.
Attention: Amy Rubin
Director, Regulatory Affairs
Harborside Financial Center
Plaza Three, Suite 602
Jersey City, NJ 07311

Dear Ms. Rubin:

Please refer to your Labeling Supplement-Changes Being Effected, dated October 17, 2000, received October 19, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flumadine® (Rimantadine HCl) Tablets and Syrup.

Reference is also made to the August 22, 2000 teleconference between yourself and members of the Division of Antiviral Drug Products, during which you agreed to revise the *Geriatric Use* section of the Flumadine® label.

This Labeling Supplement-Changes Being Effected provides for the requested revisions to the *Geriatric Use* section of the Flumadine® package insert, in accordance with the Final Rule published in the Federal Register on August 27, 1997 and 21CFR 201.57(f)(10) Geriatric Use.

We have completed review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Virginia L. Yoerg, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation 4
Center for Drug Evaluation and Research

Attachment: Labeling-Changes Being Effected dated October 17, 2000