



NDA 19-649/S-014

Forest Laboratories, Inc.
Attention: Linda Kunka
Manager, Regulatory Affairs
34 Exchange Place
Plaza 3, Suite 602
Jersey City, NJ 07311

Dear Ms. Kunka:

Please refer to your supplemental new drug application dated September 3, 2008 and received September 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flumadine (rimantadine hydrochloride) Tablets.

We acknowledge receipt of your submission dated November 11, 2008.

This supplemental new drug application provides a statement regarding resistance mutations in the INDICATIONS AND USAGE section of the Package Insert. These revisions were requested by FDA on July 25, 2008. Revisions to the label were also made to reflect the withdrawal of the syrup formulation (NDA 19-650), to revise the DOSAGE AND ADMINISTRATION section regarding use in children less than 10 years of age and to include a statement regarding potential concurrent bacterial infection in the PRECAUTIONS section.

We completed our review of this application as amended, and it is approved, effective on the date of this letter for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

The final printed labeling (FPL) must be identical to the enclosed labeling.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Elizabeth Thompson, MS, Regulatory Project Manager, at (301) 796-0824.

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 (clean copy of approved label)

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

/s/

Kendall Marcus

11/21/2008 11:52:26 AM