



NDA 19-649/S-015

SUPPLEMENT APPROVAL

Caraco Pharmaceutical Laboratories Ltd.
Attention: Veeranna Lolla, RAC
Associate Director, Regulatory Affairs
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Mr. Lolla:

Please refer to your supplemental new drug application dated August 21, 2009 and received August 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FLUMADINE (rimantadine hydrochloride) 100 mg tablets.

We also acknowledge receipt of your submissions dated August 25, 2009, September 22, 2009, October 20, 2009, December 9, 2009, March 2, 2010, and March 25, 2010.

This "Prior Approval" supplemental new drug application provides for the following revisions to the package insert:

- CLINICAL PHARMACOLOGY, Microbiology subsection to include information on resistance and cross-resistance and the results of a pharmacokinetic study in renal impairment subjects. The information on renal impairment subjects was also included in the PRECAUTIONS section.
- INDICATIONS AND USAGE to include information clarifying the population ages for treatment in adults (17 years and older), prophylaxis in children (1-16 years of age) and elderly (65 years of age and older).
- PRECAUTIONS to update the information on cimetidine drug-drug interaction studies and to add the results of the carcinogenicity studies and the Repeat Segment II teratology studies in rabbits.
- DOSAGE AND ADMINISTRATION to update the information for treatment of adults, prophylaxis for children and adults, and to add directions for compounding and storage information for an oral suspension.

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

CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that includes the changes approved in this supplemental application.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

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 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 <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

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
5600 Fishers Lane, Room 12B05
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 Robert G. Kosko, Jr., Regulatory Project Manager, at (301) 796-3979 or at the Division's main number (301) 796-1500.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19649	SUPPL-15	CARACO PHARMACEUTICAL LABORATORIES LTD	FLUMADINE (RIMANTADINE HCL) TABLETS

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

/s/

VICTORIA L TYSON
04/05/2010

KENDALL A MARCUS
04/05/2010