DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22363/S-002 **SUPPLEMENT APPROVAL**

Kowa Pharmaceuticals America, Inc.
US Agent for Kowa Company Limited
Attention: John M. Ostrander, Ph.D.
Senior Director, Regulatory Affairs
530 Industrial Park Blvd
Montgomery, AL 36117

Dear Dr. Ostrander:

Please refer to your Supplemental New Drug Application (sNDA) dated December 4, 2009, received December 11, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Livalo (pitavastatin) Tablets, 1 mg, 2 mg, and 4 mg.

We acknowledge receipt of your submission dated May 10, 2010, containing revised labeling.

This "Prior Approval" supplemental new drug application provides for a change to the graphics of the information contained on the tablet blister cards and the sample boxes (2 mg and 4 mg tablets, 7-count samples).

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

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22363/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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 Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Eric Colman, M.D.
Deputy Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURES: 7-count sample blister cartons, 2 mg, 4 mg
7-count sample blister cards, 2 mg, 4 mg

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22363	SUPPL-2	KOWA RESEARCH INSTITUTE INC	LIVALO TABLETS

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

/s/

ERIC C COLMAN
06/01/2010