DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-127/S-013

Meda Pharmaceuticals Inc.
Attention: Preena Modi
Manager, Regulatory Affairs
265 Davidson Avenue, Suite 300
Somerset, NJ 08873-4120

Dear Ms. Modi:

Please refer to your supplemental new drug application dated February 29, 2008, received March 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Optivar® (azelastine hydrochloride ophthalmic solution).

We acknowledge receipt of your submission dated June 25, 2008.

This "Prior Approval" supplemental new drug application provides for a new unit dose [redacted] package configuration for the drug product.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on June 25, 2008.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed, the enclosed labeling.

- Please include a statement in the "How Supplied" Section that notes the 0.2 mL foil pouch will be distributed as a professional sample only.

This revision is a term of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved NDA 21-127/S-013**."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted 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 21-127/S-013**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Hasmukh Patel

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