



NDA 21-127/S-007 & S-008

MedPointe Pharmaceuticals  
MedPointe Healthcare, Inc.  
Attention: Carol A. Sax  
Associate Director, Regulatory Affairs  
265 Davidson Avenue, Suite 300  
Somerset, NJ 08873-4120

Dear Ms. Sax:

Please refer to your supplemental new drug applications dated October 17, 2002, for S-007 and October 16, 2002, for S-008, both received October 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Optivar (azelastine hydrochloride ophthalmic solution) 0.05%.

We acknowledge receipt of your submissions dated June 10, and October 29, 2003, for S-007, and your submissions dated June 10 and November 25, 2003, and March 11 and 30, 2004, for S-008.

Your submission of October 29, 2003, constituted a complete response to our June 3, 2003, action letter for S-007. Your submission of March 30, 2004, constituted a complete response to our action letter of June 3, 2003, for S-008.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the container labeling, carton labeling, and package insert, for the 3 mL physician sample in S-007, and the 6 mL commercial product in S-008.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the package insert (enclosed), carton and container labeling submitted November 25, 2003, to S-008, and identical to the carton and container labeling submitted October 29, 2003, to S-007.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 21-127/S-007 and S-008." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products, HFD-550, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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

MEDWATCH, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 Nancy Halonen, Project Manager, at (301) 827-2090.

Sincerely,

*{See appended electronic signature page}*

Wiley A. Chambers, M.D.  
Deputy Director  
Division of Anti-Inflammatory, Analgesic,  
and Ophthalmic Drug products, HFD-550  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure

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

/s/

-----  
Wiley Chambers  
4/30/04 03:42:06 PM