CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-203

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-203

MedPointe Pharmaceuticals
265 Davidson Avenue, Suite 300
Somerset, NJ 08873-4120

Attention: Richard Fosko, RPh, MPH
Director, Regulatory Affairs

Dear Mr. Fosko:

Please refer to your new drug application dated July 30, 2007, received July 31, 200, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for azelastine hydrochloride nasal spray.

We acknowledge receipt of your submissions dated August 16, September 13, and 17, October 26, and December 10, and 13, 2007, and January 14, and 23, February 12, 20, and 29, March 18, and 26, April 18, and 25, and May 20, 2008.

We also acknowledge receipt of your submission dated April 24, 2008. This submission was not reviewed for this action. You may incorporate this submission by specific reference as part of your response to the deficiencies cited in this letter.

We completed our review and find the information presented is inadequate. Therefore, the application is not approvable under section 505(d) of the Act and 21 CFR 314.125(b). The deficiencies are summarized as follows: b(4)

1. The data from the submitted clinical studies are not adequate to establish efficacy and safety of ——— for the relief of symptoms of vasomotor rhinitis for patients 12 years of age and older.

2. The data from the submitted clinical studies are not adequate to establish efficacy and safety of ——— for relief of symptoms of seasonal allergic rhinitis for patients 5 to 11 years of age. b(4)

3. [redacted] b(4)

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, contact Colette Jackson, Regulatory Health Project Manager, at (301) 796-1230.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Director
Division of Pulmonary and Allergy Products
Office of Drug Evaluation II
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/

Badrul Chowdhury
5/30/2008 11:57:10 AM