DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-114/S-017

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

Attention: Richard Fosko, R.Ph., MPH
Director, Regulatory Affairs

Dear Mr. Fosko:

Please refer to your supplemental new drug application(s) dated April 23, 2007, received April 24, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Astelin® (azelastine hydrochloride) Nasal Spray, 137 mcg.

This "Changes Being Effected" supplemental new drug application provides for the addition of the terms "palpitations" and "atrial fibrillation" to the postmarketing section of the ADVERSE EVENTS section of the package insert.

We have completed our review of this application, as amended. This application 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 April 23, 2007.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Philantha Bowen, Regulatory Project Manager, at (301) 796-2466.

Sincerely,

{See appended electronic signature page}

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

8/10/2007 12:02:16 PM