DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 00-793 / S-025

MedPointe Pharma, MedPointe Healthcare, Inc.
265 Davidson Avenue Suite 300
Somerset, NJ 08873-4120

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

Dear Mr. Fosko:

Please refer to your supplemental new drug application dated September 5, 2007, received September 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Butisol Sodium, oral solution.

Your submission of September 5, 2007 constituted a complete response to our March 5, 2007 action letter.

This "Changes Being Effected" supplemental new drug application provides for class labeling changes in the sedative-hypnotic drug group, specifically in the WARNINGS, PRECAUTIONS, DRUG ABUSE AND DEPENDENCE, and Information for patients sections.

We have completed our review of this application. This application is 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 enclosed labeling (text for the package insert), submitted September 5, 2007, and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 00-793/S-025**." Approval of this submission by FDA is not required before the labeling is used.

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 Cathleen Michaloski, BSN, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Director, Division of Neurology Products
Office of Drug Evaluation 1
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/

Russell Katz

9/28/2007 03:39:46 PM