DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 11-792/s-041

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

Attention: Michael Bernhard, Ph.D.
Senior Director, Regulatory Affairs

Dear Dr. Bernhard:

Please refer to your supplemental new drug application dated November 10, 2006, received November 13, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for SOMA (carisoprodol), 250 mg Tablets.

We acknowledge receipt of your submissions dated January 9, February 1 and 8, March 2 and 27, April 3, 12, 13, and 24, May 10, June 6 and 14, July 10 and 17, August 8 and 16 and September 4 and 6, 2007.

This supplemental new drug application provides for the use of SOMA (carisoprodol), 250 mg Tablets for the relief of discomfort associated with acute, painful musculoskeletal conditions.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with minor editorial revisions indicated in the enclosed labeling.

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 the enclosed labeling text for the package insert. 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 11-792/s-041."

Carton and Immediate Container Labels

We acknowledge your July 10, 2007, submission containing final printed carton and container labels.

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

Pediatric Research Equity Act (PREA)

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

Promotional Materials

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

Letters to Health Care Professionals

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 an electronic copy of the letter to both this NDA and to the following address:

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

Stability/Shelf Life

An expiration dating period of 36 months is granted for SOMA, 250 tablets.

Reporting Requirements

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 Sharon Turner-Rinehardt, Regulatory Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

Rigoberto Roca, M.D.
Deputy Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosures: Package Insert
Immediate Container Label
Carton Label

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

/s/

Rigoberto Roca

9/13/2007 05:17:47 PM