



NDA 11-792/S-035

MedPointe Pharmaceuticals
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 May 14, 1998, received May 15, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Soma (carisoprodol) Tablets.

We acknowledge receipt of your submission dated May 26, 2005, which constituted a complete response to our May 12, 2003, action letter.

This supplemental new drug application provides for extensive revisions to the Package Insert.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert agreed upon in your email dated June 6, 2006.

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 11-792/S-035.**" 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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 Parinda Jani, Chief, Project management Staff, at (301) 796-1232.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
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/

Parinda Jani

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