DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 12-366/S-031

Meda Pharmaceuticals, Inc.
265 Davidson Avenue, Suite 300
Somerset, NJ 08873

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

Dear Mr. Fosko:

Please refer to your supplemental new drug application dated October 18, 2007, received October 19, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Soma Compound with Codeine.

This supplemental new drug application provides for the addition of new language for Ultra-rapid Metabolizers of Codeine and Nursing Mothers to the **PRECAUTIONS** section of the label as well as the updated language for Soma Compound approved in NDA 11-792/s-041.

We have completed our review of this application, 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.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, designate this submission "**FPL for approved supplement NDA 12-366/S-031**." 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Health Project Manager, at (301) 796-2254.

Sincerely,

{See appended electronic signature page}

Bob A. 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/

Rigoberto Roca
10/23/2008 05:42:10 PM
for Bob Rappaport, M.D.