DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011792/S-046

SUPPLEMENT APPROVAL

Meda Pharmaceuticals, Inc.
265 Davidson Ave. Suite # 400
Somerset, NJ 08873-4120

Attention: Cindy Yayac
Senior Manager, Regulatory Affairs

Dear Ms. Yayac:

Please refer to your Supplemental New Drug Application (sNDA) dated February 23, 2013, received February 25, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Soma (carisoprodol) Tablets.

This "Changes Being Effected" supplemental new drug application provides for revised Carton and Container labels to add the scheduling of carisoprodol.

Reference is also made to your email communication dated February 19, 2015, in which you committed to make the following changes:

For the 100 count and 30 count Container Labels, and Carton Labeling for the 250 mg Tablets, you will

1. Relocate the controlled substance symbol away from the proprietary name so that it does not get misinterpreted as a part of the proprietary name, or as the letter "c" or "o". You will ensure that the size and location of this symbol remains in accordance with 21 CFR 1302.04.

2. Revise the proprietary name, the established name and the strength to read as follows:

Soma
Carisoprodol Tablets, USP
250 mg

You have agreed to implement these changes at the next printing of the labels and labeling or within 6 months of receipt of the communication.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, with the changes listed above.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the enclosed carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 011792/S-046**." Approval of this submission by FDA is not required before the labeling is used.

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

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

Sincerely,

{See appended electronic signature page}

Sharon Hertz, MD
Acting Division Director
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

SHARON H HERTZ
02/23/2015