DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011792/S-43 **SUPPLEMENT APPROVAL**

Meda Pharmaceuticals, Inc.
265 Davidson Avenue, Suite # 300
Somerset, NJ 08873-4120

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

Dear Mr. Fosko:

Please refer to your supplemental new drug application dated September 18, 2009, received September 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Soma (carisoprodol) 250 mg and 350 mg Tablets.

We acknowledge receipt of your submissions dated October 13 and October 26, 2009.

Reference is also made to our letter dated August 19, 2009 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Soma. This information pertains to the risks of abuse potential and motor vehicle accidents in patients using Soma.

This supplemental new drug application provides for revisions to the labeling for Soma (carisoprodol) Tablets consistent with our August 19, 2009 letter and our October 21, 2009 teleconference. The agreed upon changes to the language included in our August 19, 2009 Safety Labeling Change Notification letter and discussed during our October 21, 2009 teleconference include revisions to the **WARNINGS AND PRECAUTIONS** and **DRUG ABUSE AND DEPENDENCE** and **PATIENT COUNSELING INFORMATION** sections of the package insert (additions are noted by underline and deletions are noted by ~~strikethrough~~).

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

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)(1)(i)] 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. For administrative purposes, please designate this submission, "SPL for approved NDA 011792/S-(b)(4).

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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 http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related 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
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Tanya Clayton, Regulatory Project Manager, at (301) 796-0871.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D., M.H.S.
Deputy Director for Safety
Division of Anesthesia, Analgesia, and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-11792	SUPPL-43	MEDA PHARMACEUTICALS MEDA PHARMACEUTICALS INC	SOMA

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

/s/

LARISSA LAPTEVA
11/17/2009