



NDA 12365/39  
NDA 12366/33

**SUPPLEMENT APPROVAL**

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

Attention: Cindy Yayac, Senior Manager  
Regulatory Affairs

Dear Ms. Yayac:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 2, 2012, received February 3, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Soma® Compound (carisoprodol and aspirin) Tablets and Soma® Compound with Codeine (carisoprodol, aspirin, and codeine phosphate) Tablets.

We acknowledge receipt of your amendments dated December 10, 2012, and January 14, 2013.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the labeling to update the scheduling of carisoprodol.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

### **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 Philantha Bowen, Senior Program Management Officer, at (301) 796-2466.

Sincerely,

*{See appended electronic signature page}*

Lydia Gilbert-McClain, M.D.  
Deputy Director  
Division of Pulmonary, Allergy, and Rheumatology  
Products  
Office of Drug Evaluation  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LYDIA I GILBERT MCCLAIN  
01/31/2013