DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021997/S-005 **SUPPLEMENT APPROVAL**

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

Attention: Ms. Cindy Yayac
Senior Manager, Regulatory Affairs

Dear Ms. Yayac:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on February 6, 2013, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Edluar (zolpidem tartrate) sublingual tablets, 5 mg and 10 mg.

We also refer to our letter dated January 9, 2013, notifying you, under Section 505(o)(4) of the FDCA, of new safety information to be included in the labeling for zolpidem tartrate. This information pertains to new dosing recommendations and safety warnings related to the risk of next-day psychomotor impairment.

In that letter, we notified you that the following sections of labeling should be revised based on that new safety information related to the risk of next-day psychomotor impairment: Recent Major Changes, Dosage and Administration, Drug Interactions, Use in Specific Populations, and Patient Counseling Information. The specific text for the Dosage and Administration section that we required at that time was as follows:

2 DOSAGE AND ADMINISTRATION

~~The dose of Ambien should be individualized~~ Use the lowest dose effective for the patient.

2.1 Dosage in adults

~~The recommended dose for adults is 10 mg once daily immediately before bedtime. The total Ambien dose should not exceed 10 mg per day.~~ The recommended dose is 5 mg for women and either 5 or 10 mg for men. The 5 mg dose can be increased to 10 mg if needed, but the higher dose is more likely to impair next morning driving and other activities that require full alertness. The recommended doses for women and men are different because women clear zolpidem from the body at a lower rate than men.

The total Edluar dose should not exceed 10 mg once daily immediately before bedtime.

During a discussion period following receipt of your February 6, 2013 supplement, we requested further revisions to this section of labeling. The final text that we agreed on is as follows:

2 DOSAGE AND ADMINISTRATION

~~The dose of Ambien should be individualized~~

2.1 Dosage in Adults

~~The recommended dose for adults is 10 mg once daily immediately before bedtime. The total Ambien dose should not exceed 10 mg per day.~~ Use the lowest effective dose for the patient. The recommended initial dose is 5 mg for women and either 5 or 10 mg for men, taken only once per night immediately before bedtime with at least 7-8 hours remaining before the planned time of awakening. If the 5 mg dose is not effective, the dose can be increased to 10 mg. In some patients, the higher morning blood levels following use of the 10 mg dose increase the risk of next day impairment of driving and other activities that require full alertness [see Warnings and Precautions (5.1)]. The total dose of Edluar should not exceed 10 mg once daily immediately before bedtime.

The recommended initial doses for women and men are different because zolpidem clearance is lower in women.

We have completed our review of the supplemental application. The application is 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 inserts, text for the and Medication Guides), 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).

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

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 Cathleen Michaloski, BSN, MPH, Sr. Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Eric Bastings, M.D.
Deputy Division Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling for NDA 21997

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

/s/

ERIC P BASTINGS
04/19/2013