DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21793/S-011

SUPPLEMENT APPROVAL

Meda Pharmaceuticals Inc.
Attention: Mary Alonso
Director Regulatory Affairs
200 North Cobb Parkway
Bldg 400, Suite 428
Marietta, GA 30062

Dear Ms. Alonso:

Please refer to your Supplemental New Drug Application (sNDA) dated October 4, 2011, and received October 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Reglan (metoclopramide) orally disintegrating tablets, 5 mg and 10 mg.

We acknowledge receipt of your amendment dated October 27, 2011.

This "Prior Approval" supplemental new drug application provides for changes to the Medication Guide in which "TD" is spelled out to read "Tardive Dyskinesia".

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.

CONTENT OF LABELING

We refer to your request for a waiver, under 21 CFR 314.90(a), from the requirement at 21 CFR 314.50(l)(i) to submit, as part of your supplemental application, the content of labeling (COL) in electronic format due to your July 12, 2011, request to withdraw approval of this NDA.

We have reviewed your request and have determined that a waiver is not justified for this submission. However, we are granting an extension of the date you must submit, as part of your supplemental application, the content of labeling in electronic format until such time that you intend to market this drug product again by resubmission of this NDA.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory

comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on 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.

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 Maureen Dewey, Regulatory Project Manager, at (301) 796-0845.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

JOYCE A KORVICK
11/30/2011