DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20136/S-023 **SUPPLEMENT APPROVAL**

Meda Pharmaceuticals
Attention: Richard Fosko, RPh, MPH
Directory, Regulatory Affairs
265 Davidson Avenue, Suite 300
Somerset, NJ 08873-4120

Dear Mr. Fosko:

Please refer to your new supplemental drug application (sNDA) dated October 22, 2009 for Demadex, (torsemide) 5, 10, 20, and 100 mg Tablets.

This Prior Approval supplemental new drug application provides for the following revisions to the Adverse Reactions, Post-Marketing section of the package insert:

> The following adverse reactions have been identified during the post approval use of the Demadex. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Adverse reactions reported include the following: leukopenia, thrombocytopenia.
>
> Serious skin reactions (*i.e.*, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported in association with torsemide use.

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

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 20136/S-023.

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, please call:

Michael Monteleone, MS
Regulatory Project Manager
(301) 796 – 1952

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure
Approved labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20136	SUPPL-23	MEDA PHARMACEUTICALS INC	DEMADEX (TORSEMIDE) TABS.

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

/s/

MARY R SOUTHWORTH
01/27/2010