CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021463Orig1s000

REMS

NDA 21-463 FORTESTA™ (testosterone) gel for topical use CIII

Class of Product: Steroid Androgen

Endo Pharmaceuticals Inc. (Endo)
100 Endo Boulevard
Chadds Ford, PA 19317
Phone: (610) 558-9800; Fax: (484) 840-4290

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL

The goal of this REMS is to inform patients about the serious risks associated with the use of FORTESTA (testosterone) Gel.

II. REMS ELEMENTS

A. Medication Guide

Endo Pharmaceuticals Inc. will ensure that a currently approved Medication Guide will be dispensed with each FORTESTA (testosterone) Gel prescription dispensed in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

Endo Pharmaceuticals Inc. will submit REMS assessments to FDA 18 months, 3 years and 7 years from the date of the approval of the REMS. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Endo will submit each assessment so that it will be received by FDA on or before the due date.

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/s/

GEORGE S BENSON
12/29/2010