OREXIGEN®

10 May 2017

PMR 2778-1:
RESPONSE TO PREA
NON-COMPLIANCE LETTER

Jean-Marc Guettier, M.D.
Director, Division of Metabolism and Endocrinology Products
Center for Drug Evaluation and Research
Food and Drug Administration
Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

ATTN: Patricia Madara, Regulatory Health Project Manager

Re: NDA 200063: RESPONSE TO PREA NON-COMPLIANCE LETTER
CONTRAVE® (naltrexone HCl and bupropion HCl) Extended-Release Tablets

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Dear Dr. Guettier:

We reference our New Drug Application (NDA 200063) for Contrave (naltrexone HCl and bupropion HCl) Extended-Release Tablets. Reference is also made to the NDA Approval Letter dated 10 September 2014 and the Notification of Non-Compliance with PREA letter dated 04 April 2017.

The final report milestone for Post-Marketing Requirement (PMR) 2778-1 was missed due to delays receiving the report from the study vendor. However, the final report has now been submitted to the above referenced NDA after alignment with the Agency on the submission contents appropriate to comply with PREA and meet the PMR milestone.

Should you have any questions, please do not hesitate to contact me.

Sincerely,

Teri E. Johnson,
Sr. Director, Regulatory Affairs
Orexigen Therapeutics, Inc.
Phone: (858) 875-8600