DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

October 21, 2013

FILE COPY

Kimberly D. Ernst
Senior Director, Regulatory Affairs
CorePharma, LLC
215 Wood Avenue
Middlesex, NJ 08846

Re: This is a correction to the acknowledgement letter of 5/23/2013

Dear Ms. Ernst:

Your petition to the Food and Drug Administration requesting FDA to determine whether Moban® Tablets, NDA 017111, manufactured by Endo Pharmaceuticals Inc. has been voluntarily withdrawn from sale for safety and efficacy reasons, was received by this office on 05/23/2013. It was assigned docket number FDA-2013-P-0631/CP1, and it was filed on 05/23/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)

FDA-2013-P-0631

ACK