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May 22, 2013

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Citizen Petition

The undersigned submits this petition under 21 CFR 10.25(a) and 21 CFR 10.30 to request the Commissioner of the Food and Drug Administration to determine whether a listed drug (Moban® Tablets, manufactured by Endo Pharmaceuticals Inc. under NDA 017111), that has been discontinued, was not discontinued for safety or effectiveness reasons. In addition, the undersigned submits this application to request permission for approval of an abbreviated new drug application (ANDA) if the listed drug was discontinued for reasons other than for safety and effectiveness.

A. Action Requested

The petitioner (CorePharma, LLC) requests that the Commissioner of the Food and Drug Administration determine whether Moban® Tablets, NDA 017111, manufactured by Endo Pharmaceuticals Inc. has been voluntarily withdrawn from sale for safety and efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration's Orange Book (http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempno.cfm) updated through April, 2013 lists Moban® (NDA 017111) as a discontinued drug. According to information received online at FDA's Drug Approvals and Databases website (http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm) under Additions/Deletions for Prescription and OTC Drug Product Lists, this product was discontinued as of May, 2010. Copies of online web pages are enclosed as Attachments 1 and 2.

Under FDA Regulations, the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety and effectiveness before an ANDA referencing the listed drug may be approved (21 CFR 314.161 (a)(1)).

CorePharma, LLC believes the reason that the innovator discontinued marketing Moban® Tablets, was strictly due to sourcing issues and not for reasons related to safety and effectiveness. CorePharma, LLC petitions FDA to determine that Endo Pharmaceuticals Inc.'s decision to discontinue Moban® Tablets was for reasons other than safety or effectiveness.

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C. Environmental Impact

A claim for categorical exclusion of the requirement for submission of an environmental assessment or environmental impact statement is made pursuant to 21 CFR 25.31.

D. Economic Impact

In accordance with 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. CorePharma hereby commits to promptly provide this information, if so requested.

E. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,

Kimberly D Ernst

Kimberly D. Ernst
Senior Director, Regulatory Affairs

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