DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 27, 2013

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

Dear Ms. Ernst:

Your petition to the Food and Drug Administration requesting the Agency to determine whether Skelaxin ® 400 mg, NDA 013217, manufactured by King Pharmaceuticals, Inc has been voluntarily withdrawn from sale for safety and efficacy reasons, was received by this office on 09/20/2013. It was assigned docket number FDA-2013-P-1199/CP1, and it was filed on 09/20/2013. 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)