DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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June 5, 2013

Joan Janulis
Vice President
Lachman Consultant Services, Inc.
Consultants to the Pharmaceutical and Allied Industries
1600 Stewart Avenue
Westbury, NY 11590

Dear Ms. Janulis:

Your petition to the Food and Drug Administration requesting that FDA determine whether PARAFLEX (chlorzoxazone) Tablets, 250 mg (Ortho McNeil Pharm, a Johnson & Johnson company), NDA 011300 has been voluntarily withdrawn from sale for safety or efficacy reasons, was received by this office on 06/05/2013. It was assigned docket number FDA-2013-P-0671/CP1, and it was filed on 06/05/2013. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)