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June 4, 2013

OVERNIGHT COURIER 6/4/13

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition, in quadruplicate pursuant to 21 C.F.R. § 10.30 and in accordance with the regulations at 21 C.F.R. § 314.161, requesting the Commissioner of the Food and Drug Administration to determine whether a listed drug has been withdrawn for safety or effectiveness for the reasons as outlined below.

A. Action Requested

Petitioner requests that the Commissioner of the Food and Drug Administration 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(chlorzoxazone) Tablets, 250 mg (Ortho McNeil Pharm, a Johnson & Johnson company), NDA 011300 has been voluntarily withdrawn from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products that are eligible for submission as abbreviated new drug applications (ANDAs). This list, referred to as the Orange Book, is divided into three sections; (1) approved prescription drug products; (2) approved over-the-counter drug products; and (3) discontinued drug products. PARAFLEX (chlorzoxazone) Tablets, 250 mg (Ortho McNeil Pharm), NDA 011300, was approved by the FDA prior to January 1, 1982. However, PARAFLEX (chlorzoxazone) Tablets, 250 mg is currently listed in the discontinued section of the Orange Book. A copy of the Orange Book's discontinued section listing PARAFLEX is provided as **Attachment 1**. The Petitioner is unaware of the precise date when PARAFLEX (chlorzoxazone) Tablets, 250 mg moved from the approved prescription drug product section to the discontinued drug product section of the Orange Book. The Petitioner believes that the innovator has discontinued marketing the drug product for commercial reasons.

It should be noted that Janssen R&D (a Johnson & Johnson company) has not withdrawn its PARAFON FORTE DSC (chlorzoxazone) Tablets, 500 mg drug product (NDA 011529) which contains the same active ingredient, but at a higher dosage strength than PARAFLEX (chlorzoxazone) Tablets, 250 mg. There are also several ANDAs listed in the approved section of the Orange Book for the 500 mg dosage strength, as well as an ANDA for both a 375 mg and 750 mg dosage strength of Chlorzoxazone Tablets. A copy of the electronic Orange Book's approved prescription drug product section listing PARAFON FORTE DSC and ANDA approved drug products is provided as **Attachment 2**.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or discontinued from sale for reasons of safety of effectiveness. (21 C.F.R. § 314.162) The regulations also provide that the Agency must make a determination as to whether a listed

drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. (21 C.F.R. § 314.161(a)(1))

As stated above, at the time of submission of this Petition, there is no evidence that the innovator is currently marketing its product, PARAFLEX (chlorzoxazone) Tablets, 250 mg. Therefore, because the product has been discontinued from marketing, the Petitioner requests that the FDA determine whether the application holder's decision to discontinue PARAFLEX (chlorzoxazone) Tablets, 250 mg, as approved under NDA 011300, was for reasons of safety or effectiveness. Such a determination will permit the FDA to approve ANDAs for that drug product.

Should the NDA holder reintroduce PARAFLEX (chlorzoxazone) Tablets, 250 mg to the market after submission of this Petition and prior to FDA's response, and there is evidence that the product is available in the marketplace, the Petitioner will consider this Petition moot, and will at that time take appropriate action to request withdrawal of the Petition.

C. Environmental Impact

The Petitioner claims a categorical exclusion under 21 § C.F.R. 25.31.

D. Economic Impact

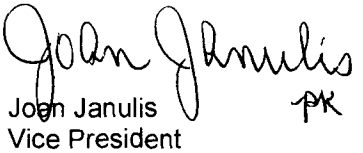
Petitioner will, upon request by the FDA Commissioner, submit economic impact information in accordance with 21 C.F.R. § 10.30(b).

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 Petitioner that are unfavorable to the Petition.

Respectfully submitted.

Sincerely,



Joan Janulis
Vice President

JJ/pk

Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, Discontinued Drug Product Section, accessed May 31, 2013
2. Approved Drug Products with Therapeutic Equivalence Evaluations, Approved Prescription Drug Product Section, accessed May 31, 2013

A43 Petition Chlorzoxazone

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