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December 15, 2006

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**RE: Request for Assessment of Safety and Effectiveness**
**Methotrexate Injection, USP**
**Eq. 500 mg base/20 mL vial (25 mg/mL)**

## CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in duplicate pursuant to 21 CFR 10.30 and in accordance with the regulation of 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons, as outlined below.

## A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Methotrexate Injection, USP, Preservative Free, Eq. 500 mg base/20 mL, NDA No. 11-719 held by Mayne Pharma USA has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons. In addition, we request the Commissioner to confirm the eligibility of Methotrexate Injection, USP, Preservative Free, Eq. 500 mg base/20 mL (25 mg/mL) as a Reference Listed Drug such that it will be allowed to form the basis of an ANDA.

## B. Statement of Grounds

The *Electronic Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluation* (Electronic Orange Book) identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the Act). The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.

In August 1959, the original NDA no. 11-719 was approved. In April 2005, Mayne Pharma USA received approval of a new formulation of Methotrexate Injection, USP, Preservative Free, Eq. 500 mg base/20 mL along with other configurations for treatment of the same indications that are claimed by the previously approved formulation.

Recently, Mayne Pharma's Methotrexate Injection, USP, Eq. 500 mg base/20 mL vial (25 mg/mL) was moved to the Discontinued Drug Products section of the *Electronic Orange Book* (Attachment 1, page 2). Mayne Pharma's product is the only methotrexate product in the desired configuration of Eq. 500 mg base/20 mL, listed in both the prescription drug list (Attachment 2) or the discontinued list (Attachment 1).

Enclosed is the package insert approved in April 2005 that includes both current and discontinued Methotrexate Injection, USP products, which are marketed by Mayne Pharma U.S.A. (Attachment 3). Since the approval of the configuration on April 13, 2005, no specific MedWatch notices or other labeling updates have been posted for Mayne Pharma's Methotrexate Injection products.

## C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

## D. Economic Impact

Pursuant to 21 CFR 10.0(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, 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 petition relies, and that includes representative data and information known to the petitioner, which is unfavorable to the petition.

We trust you will find this citizen petition satisfactory for your review. If there are any questions concerning this request, please do not hesitate in contacting me at (949) 455-4728. I can also be contacted by facsimile at (949) 583-7351.

Sincerely,

Tania Hoffman

Tania Hoffman
Project Specialist, Regulatory Affairs
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