LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

1600 STEWART AVENUE, WESTBURY, NY 11590
(516) 222-6222 • FAX (516) 683-1887

February 10, 2006

OVERNIGHT COURIER 2/10/06

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 on behalf of a client in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness for the reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Doxycycline Tablets, 75 mg (ANDA 65-070), held by Par Pharmaceuticals has been voluntarily withdrawn from sale for safety or efficacy reasons.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). The list, referred to as the Orange Book, contains all FDA-approved drug products. Doxycycline Tablets, 75 mg were approved by the FDA on 12/30/02 and were, upon approval, considered to be "listed drug products" and listed in the Orange Book. It should also be noted that FDA has also approved Doxycycline Tablets in strengths of 50 mg, 100 mg and 150 mg in ANDA 65-070 that are marketed today. The current listing of the product in the electronic Orange Book, accessed February 10, 2006, does not list the 75 mg strength tablet in the active section of the Orange Book. Rather, the 75 mg Doxycycline Tablet is found in the "Discontinued" section of the Orange Book. It is believed that the ANDA holder has either never marketed the product or discontinued sale of the 75 mg strength solely for marketing reasons. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale." (65 FR 38561)

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or

effectiveness (21 CFR 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 CFR 314.161(a)(1)).

As stated above at the time of submission of this petition, the 75 mg Doxycycline Tablet appears in the discontinued section of the Orange Book, and it thus has either been discontinued from sale or never marketed. Therefore, it is requested that the FDA determine whether the appearance of the 75 mg ANDA product in the discontinued section of the Orange Book represents a discontinuation of marketing for reasons of safety or effectiveness reasons.

Should the ANDA holder commence marketing of Doxycycline Tablets, 75 mg after the submission of this petition and prior to FDA response and there is evidence that the product is available in the marketplace, LCS will consider the petition moot. We will at that time take appropriate action to request withdrawal of the petition.

C. Environmental Impact

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

D. Economic Impact

Pursuant to 21 CFR 10.30(b) economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted, if so requested.

E. Certification

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

Respectfully submitted,

Robert Pollock

Robert W. Pollock
Senior Vice President

RWP/pk

cc: Martin Shimer (Office of Generic Drugs)

M33P6041