

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

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

May 5, 2004

**OVERNIGHT COURIER 5/5/04**

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 Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR 10.30 on behalf of a client requesting the Commissioner of the Food and Drug Administration to declare that the drug product, Doxycycline Monohydrate Capsules, 150 mg, is suitable for consideration in abbreviated new drug applications (ANDAs).

**A. Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration declare that Doxycycline Monohydrate Capsules, 150 mg, are suitable for submission as an ANDA. The listed reference drug product, upon which this petition is based, is Monodox® Capsules (Doxycycline Monohydrate), 100 mg (Oclassen Pharmaceuticals). The petitioner also references Monodox Capsules, 50 mg, in support of this petition. Therefore, the petitioner seeks a change in strength (from 100 mg to 150 mg), from that of the listed drug product.

**B. Statement of Grounds**

The Federal Food, Drug and Cosmetic Act provides for the submission of an Abbreviated New Drug Application for a drug product that differs in dosage strength from that of the listed drug provided the FDA has approved a petition that proposed filing such an application.

The reference-listed drug (RLD), Monodox Capsules manufactured by Oclassen Pharmaceuticals, is a capsule product containing 100 mg of Doxycycline Monohydrate. See listing on page 3-134 of the 24<sup>th</sup> Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations (Attachment 1). The proposed drug product represents a capsule dosage form containing 150 mg of Doxycycline Monohydrate. The petition is thus seeking a change in strength (from 100 mg to 150 mg), from that of the reference-listed drug.

The acceptability of the proposed 150 mg strength is contemplated in the labeling of the listed drug. Doses of 300 mg are indicated in the treatment of primary and secondary syphilis. The approved labeling of the listed drug states that daily dose of 300 mg of Doxycycline Monohydrate should be administered in divided doses. A 150 mg strength allows dosing of a

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single capsule twice daily. A single 300 mg dose is also indicated for the treatment of uncomplicated gonococcal infections in adults. One of the treatment recommendations for this indication is 300 mg as a single dose followed by another 300 mg dose in one hour which currently would require a patient to take three capsules of the 100 mg strength product for each of the two recommended doses. A 150 mg capsule would permit administration of only two single capsules per dose. The reduction in dosage units that must be taken would aid patients that have trouble taking multiple dosage units and may improve compliance with the prescribed regimen.

There are no proposed changes in labeling with the exception of the obvious changes in strength sought in this petition. Draft labeling for the proposed product is included in Attachment 2, and the reference-listed drug product's approved labeling is provided in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength from 100 mg to 150 mg, for Doxycycline Monohydrate should raise no questions of safety or effectiveness, and the Agency should approve the petition.

**C. Environmental Impact**

The petitioner claims a categorical exclusion under 21 CFR 25.31.

**D. Economic Impact**

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the Agency.

**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, which are unfavorable to the petition.

Respectfully submitted,

  
Robert W. Pollock  
Vice President

RWP/pk

- Attachments:
1. Approved Drug Products with Therapeutic Equivalence Evaluations, 24<sup>th</sup> Edition, Page 3-134
  2. Draft Insert Labeling Proposed for Doxycycline Capsules, 150 mg
  3. Labeling for Monodox®, Revised January 1999

cc: Emily Thakur (OGD)

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