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October 13, 2006

OVERNIGHT COURIER 10/13/06

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, 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 Tablets, 125 mg, is suitable for consideration in an abbreviated new drug application (ANDA).

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration declare that the drug product, Doxycycline Monohydrate Tablets, 125 mg, is suitable for submission as an ANDA. The listed reference drug (RLD) product upon which this petition is based is Adoxa® Tablets (Doxycycline Monohydrate), 150 mg (see Attachment 1, current listing of the electronic Approved Drug Products with Therapeutic Equivalence Evaluations ["The Orange Book"]), citing the listing of the reference product. The application number of the RLD is 65-070 held by Par Pharmaceutical, Inc. Therefore, the petitioner seeks a change in strength (from 150 mg to include a new intermediate 125 mg strength) from that of the listed drug product.

B. Statement of Grounds

The reference-listed drug (RLD) product is a tablet product containing 150 mg of Doxycycline Monohydrate. In addition, other approved strengths of the RLD include 50 mg, 75 mg, and 100 mg tablets. The proposed drug product represents the same tablet dosage form of a strength that is directly between two approved strengths of the RLD (i.e., 100 mg and 150 mg) and contains the same active ingredient. The petition is thus seeking a change in strength (from 150 mg to include a 125 mg tablet strength) from that of the reference-listed drug.

The dosing in the approved labeling of the RLD ranges from 50 mg to 300 mg, which may be given in divided doses or in a single dose depending, in some instances, on the age or weight of the patient and/or the particular disease state being treated. The FDA has previously approved petitions for intermediate strengths of doxycycline and other tetracycline derivatives to permit dosing either on a mg/kg basis, or to aid the physician in selecting an intermediate dose between two approved doses to mitigate some of the untoward side effects, such as nausea, vomiting or any of the vestibular effects seen with some of the tetracycline derivatives. The RLD labeling contemplates dosing throughout the ranges cited above, again based on either age, weight and/or disease state being treated. The labeling of the RLD warns that: "exceeding the recommended dosage may increase the incidence of side effects." The

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addition of the 125 mg tablet strength will permit added flexibility for the prescribing physician to select an appropriate dose for a specific patient while at the same time assuring a minimal adverse event side effect profile. A copy of the reference-listed drug package insert is included in Attachment 2. Draft labeling for the proposed product is included in Attachment 3.

Therefore, the petitioner's request for the Commissioner to find that a change in strength (from 150 mg to include a 125 mg strength) 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 Pollock

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RWP/pk

Attachments:
1. Current listing of the electronic Approved Drug Products with Therapeutic Equivalence Evaluations
2. Reference-Listed Drug Package Insert
3. Draft labeling

cc: Leo Zadecky (Office of Generic Drugs)

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