



A Division of Orchid Chemicals & Pharmaceuticals Ltd.,

Date: June 13, 2006

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir / Madam:

The undersigned on behalf of Orchid Healthcare (A Division of Orchid Chemicals & Pharmaceuticals Ltd.) 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 requesting the Commissioner of the Food and Drug Administration to make determination that the discontinued formulation of Warner Chilcott's Duricef[®] (cefadroxil) Tablets 1 g was not discontinued for safety and efficacy reasons.

A. Action Requested

Orchid Healthcare (A Division of Orchid Chemicals & Pharmaceuticals Ltd.) requests the Commissioner of the Food and Drug Administration to make a determination that the discontinued formulation of Warner Chilcott's Duricef[®] (cefadroxil) Tablets 1 g was not discontinued for safety and efficacy reasons.

The Reference Listed Drug product (RLD) was Duricef[®] (cefadroxil) Tablets 1 g, the subject of NDA 050-528, held by Warner Chilcott till 2005 (as listed in the electronic Orange Book. Please refer **Attachment - 1**). The RLD Duricef[®] (cefadroxil) Tablets 1 g of Warner Chilcott was discontinued (Please refer **Attachment - 2** for the copies of the relevant pages of current Orange Book).

The applicant is requesting to determine that the discontinued formulation of the RLD Duricef[®] (cefadroxil) Tablets 1 g was not discontinued for safety and efficacy reasons.

The applicant also requests that the ANDA submitted with Duricef[®] (cefadroxil) Tablets 1 g as RLD (as was the case at that time of ANDA submission) is valid and approvable subject to meeting the Agency's requirements though the current RLD is Cefadroxil Tablets 1 g held by Ivax Pharmaceuticals. (Please refer **Attachment - 3** for the copies of the relevant pages of current Orange Book).

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B. Statement of Grounds

The Orange Book contains a list of all drug products approved by the Food and Drug Administration (FDA) which are eligible for submissions as ANDAs. The current date of the electronic Orange Book lists Duricef[®] (cefadroxil) Tablets 1 g under the Discontinued Drug Products section. It is known that any approved drug, whether or not it is on the market, is included in the Orange Book and may support an ANDA as a referenced listed drug unless or until FDA finds that it is withdrawn for safety or efficacy reasons.

It is known from the Code of Federal Regulations that when an ANDA makes reference to a discontinued label of a drug, FDA may approve the ANDA upon determination that the formulation was not withdrawn for reasons of safety or effectiveness (21 U.S.C. Section 355 (j)(6) and 21 CFR 314.122 and 314.161).

The drug product, Cefadroxil Tablets 1 g which is the subject of the ANDA relies on the presently discontinued formulation of the RLD Duricef[®] (cefadroxil) Tablets 1 g, the subject of NDA 050-528, held by Warner Chilcott. This discontinued formulation was RLD at the time of ANDA submission and was considered as basis of ANDA submission. It was therefore used for proving *in-vivo* bioequivalence for the proposed drug product Cefadroxil Tablets 1 g at the time of submission of the ANDA.

The proposed generic product is identical to the discontinued formulation of Duricef[®] (cefadroxil) Tablets 1 g. The petitioner believes that Duricef[®] (cefadroxil) Tablets 1 g was not withdrawn for the reasons of safety and efficacy. The continued presence of Cefadroxil Tablets 1 g (current RLD held by Ivax) on the market is a clear indication that the discontinued product remains safe and effective if used in accordance with the approved labeling. The petitioner therefore requests that its Cefadroxil Tablets 1 g ANDA be eligible for approval upon completion of the review process even though the currently approved RLD is Cefadroxil Tablets 1 g of Ivax Pharmaceuticals.

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.

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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,


June 13, 2006

Imtiyaz Basade
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- Attachments: (1) Copies of the relevant pages of the Orange Book
(2) Copies of the relevant pages of the current Orange Book
(3) Copies of the relevant pages of the current Orange Book