Taro Pharmaceuticals U.S.A., Inc.

April 12, 2006

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

CITIZEN PETITION

The undersigned submits this petition pursuant to section 505 (j) (2) (c) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Parts 314.55 (d) (2) and 10.30 of the Food and Drug Administration's regulations, to request the Commissioner of the Food and Drugs Administration to make a determination of ANDA suitability of Dichlorphenamide Tablets USP, 50 mg, based on the reference-listed drug, Merck's Daranide® Tablets, 50 mg. Daranide Tablets were voluntarily discontinued in May 2003 for reasons not related to the safety or effectiveness of the product. This is confirmed by (i) Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), 23rd Edition, cumulative supplement number 5: May 2003, [Exhibit 1] and (ii) a search on FDA MedWatch - Medical Product Safety Information between the years 1996 and to date.

A. Action Requested

The petitioner requests the Commissioner of the Food and Drug Administration for a change to a listed drug to a generic version of Daranide Tablets, 50 mg which was voluntarily discontinued in May, 2003 for reasons other then safety or efficacy to allow the undersigned to submit an Abbreviated New Drug Application for Dichlorphenamide Tablets USP, 50 mg.

2006P-0160

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B. Statement of Grounds

Dichlorphenamide Tablets USP, 50 mg will be the same as the discontinued reference-listed products, Merck's Daranide® Tablets, 50 mg in respect of:

(i) Active ingredient, Dichlorphenamide
(ii) Indications
(iii) Dosing regimen
(iv) Inactive ingredients
(v) Conduct an in-vitro dissolution profile testing as specified in USP 29.

Copies of Merck's Daranide® Tablets, 50 mg [Exhibit 2] and Taro's proposed labeling for Dichlorphenamide Tablets USP, 50 mg with highlighting of the changes is attached [Exhibit 3].

C. Environmental Impact

The undersigned, hereby requests a categorical exclusion under 21 CFR 25.24 (c) (1). The proposed drug product will not be administered at higher dosage levels, for longer duration, or for different indications than for the listed product.

D. Economic Impact

This information will be submitted on request of the Commissioner.

E. Advantages

Dichlorphenamide Tablets USP, 50 mg will provide the physicians flexibility in prescribing the drug for adjunctive treatment of chronic simple (open-angle) glaucoma, secondary glaucoma, and preoperatively in acute angle-closure glaucoma where delay of surgery is desired in order to lower intraocular pressure.

F. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and view 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,

A. Yacobi

Avraham Yacobi, Ph.D.
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