



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 4 2006

Food and Drug Administration
Rockville MD 20857

Avraham Yacobi, Ph.D.
President
Taro Research Institute
3 Skyline Drive
Hawthorne, NY 10532

3047 6 OCT 11 10:05

Re: Docket No. 2006P-0160/CP1

Dear Dr. Yacobi:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated April 12, 2006. Your petition requests that FDA determine whether it is suitable to file an abbreviated new drug application based on the reference listed drug Daranide (dichlorphenamide) Tablets, 50 milligrams, that was voluntarily withdrawn from sale by Merck & Co., Inc.

FDA has been unable to reach a decision on your request because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2006P-0160

LET 1