



1240 '03 MAR 18 19:15 Taro Pharmaceuticals U.S.A., Inc

March 17, 2003

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

**AMENDMENT - CITIZEN PETITION**  
**Docket Number: 02P-0498CPI**

Dear Sir or Madam:

Reference is made to the telephone conversation of the Agency. Martin Shimer dated March 14, 2003, requested us to submit an amendment to the above-mentioned petition to specify the reference strength of Warfarin Sodium Tablets.

The undersigned submits this amendment, to request the Commissioner of Food and Drugs to make a determination of ANDA suitability for a new strength of Warfarin Sodium Tablets, USP 0.5 mg, based on the reference-listed drug, Bristol-Myers Squibb's Coumadin<sup>®</sup> Tablets, 2 mg.

Should you require any additional information, please do not hesitate to contact us.

Respectfully submitted

Avraham Yacobi, Ph.D.  
President, Taro Research Institute

02P-0498

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