



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

July 8, 2003

FILE COPY

Dr. Avraham Yacobi
Taro Pharmaceuticals U.S.A., Inc.
Five Skyline Drive
Hawthorne, New York 10532

Dear Dr. Yacobi:

Your petition requesting the Food and Drug Administration to make a determination of ANDA suitability for Carbamazepine Oral Suspension USP, 200 mg/5 mL based on the reference-listed drug Tegretol Oral Suspension, 100 mg/5mL of Novartis Pharmaceuticals Corporation, was received by this office on 07/03/2003. It was assigned docket number 2003P-0304/CP 1 and it was filed on 07/08/2003. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

2003P-0304

ACK 1