



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

March 13, 2001

Naomi Joy Levan Halpern
Olsson, Frank and Weeda, P.C.
1400 Sixteenth Street, N.W.
Suite 400
Washington, DC 20036-2220

Dear Ms. Halpern:

Your petition requesting the Food and Drug Administration to determine that Amiodarone Hydrochloride 100 mg tablets are suitable for an Abbreviated New Drug Application (ANDA), was received by this office on 03/13/01. It was assigned docket number 01P-0125/CP 1 and it was filed on 03/13/01. 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,

A handwritten signature in cursive script that reads "Gloria Ortega".

Gloria Ortega
Dockets Management Branch

01P-0125

ACK 1