



Food and Drug Administration  
Rockville MD 20857

# FILE COPY

August 01, 2002

Ms. Rosalie A. Lowe  
Gensia Sicor Pharmaceuticals, Inc.  
19 Hughes  
Irvine, CA 92618-1902

Dear Ms. Lowe:

Your petition requesting the Food and Drug Administration to allow submission of an ANDA for Amiodarone Hydrochloride Injection in a strength of 450 mg/9 ml, single use vial, was received by our office on 08/01/02. It was assigned docket number 02P-0346/CP 1 and it was filed on 08/01/02. 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

02P-0346

ACK1