DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

September 20, 2001

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 permit a change in the total drug content (strength) to allow for submission of supplement to an ANDA for Propofol Injectable Emulsion 1% with 0.025% Sodium Metabisulfite in a strength of 2000 mg/200mL, single use vial, was received by our office on the 09/18/01. It was assigned docket number 01P-0430/CP 1 and it was filed 09/20/01. Please refer to this docket number in the future correspondence 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

01P-0430

ACK1