ANDA 75-392 September 19, 2000

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

Dear Madam:

This is in reference to your abbreviated new drug application dated May 29, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Propofol Injectable Emulsion, 1% (10 mg/mL), packaged in a 20 mL pre-filled syringe.

Reference is also made to your amendments dated June 21, July 20, August 14, and August 21, 2000.

The listed drug referenced in your application, Diprivan Injectable Emulsion, 1% of AstraZeneca UK Ltd. is subject to a period of patent protection that expires on September 22, 2015 (U.S. patents 5,714,520, 5,731,355, 5,731,356, and 5,908,869). Your application contains certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on any of the listed patents. Section 505(j)(5)(B)(iii) of the Act provides that approval of this application shall be made effective immediately unless an action is brought for infringement of one or more of the patents that are the subject of the certifications. Such action must be brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received. You have notified the agency that Gensia Sicor Pharmaceuticals, Inc. (Gensia Sicor) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for patent infringement was brought against Gensia Sicor within the statutory forty-five day period.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Propofol Injectable Emulsion, 1% (10 mg/mL), to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Diprivan Injectable Emulsion, 1% (10 mg/mL), of AstraZeneca UK Ltd.).

Under Section 506(A) of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research