DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-883/SLR-007

Encysive Pharmaceuticals
Attention: Daniel J. Thompson
6700 West Loop South
Suite 400
Bellaire, Texas 77401

Dear Mr. Thompson:

Please refer to your supplemental new drug application dated April 30, 2003, received May 1, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Argatroban Injection.

This "Changes Being Effected" supplemental new drug application provides for revising the DOSAGE AND ADMINISTRATION section of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 30, 2003.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-9334.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick
10/29/03 02:59:19 PM
for Dr. Robert Justice