DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-883/S-010

Encysive Pharmaceuticals
Attention: Daniel J. Thompson
4848 Loop Central
Suite 700
Houston, Texas 77081

Dear Mr. Thompson

Please refer to your supplemental new drug application dated October 9, 2003, received October 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Argatroban Injection.

We acknowledge receipt of your submissions dated October 12, 2004. These submissions constituted a complete response to our April 8, 2004 action letter.

This supplemental new drug application provides for the following changes to the package insert:

1) revision to the "Special Populations" subsection of the CLINICAL PHARMACOLOGY section,
2) revision to the OVERDOSAGE section, and
3) revision to the "Stability/Compatibility" subsection of the DOSAGE AND ADMINISTRATION section.

We have completed the review of this supplemental application, as amended. This supplemental application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert) submitted October 12, 2004.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-883/S-010**." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting 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/

Kathy Robie-Suh
4/11/05 05:18:05 PM
signing for Dr. Joyce Korvick