



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-883/SLR-009

Encysive Pharmaceuticals, Inc.
Attention: Howard Richman, DPM
4848 Loop Central Drive
Suite 700
Houston, TX 77081

Dear Dr. Richmond:

Please refer to your supplemental new drug application dated September 25, 2003, received September 26, 2003, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for Argatroban Injection.

We acknowledge receipt of your submissions dated March 7, 2005 and July 26, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions to ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION sections of the package insert to add the incidence of intracranial bleeding in ischemic stroke patients treated with Argatroban and to revise the instructions about dosage and administration.

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) identified as "AR:L7 April 2005, submitted on July 26, 2005.

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) 301-827-9334.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation

**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
9/1/2005 02:44:16 PM
signing for Dr. Joyce Korvick