CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-903

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-903

Farmacon-IL, LLC
Attention: Dr. Laszlo L. Darko
1071 Post Road East
Westport, Connecticut 06880-5361

Dear Dr. Darko:

Please refer to your new drug application (NDA) dated August 30, 2005, received September 1, 2005, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for NeoProfen® (ibuprofen lysine) 10 mg/mL IV Injection.

We acknowledge receipt of your submissions dated April 13 (2) & 27; June 24, 27 & 28; July 12, 15 & 21; August 4, 11 & 30 (2); September 19; October 26; November 1, 8, 10, 15 & 16; December 21, 2005; January 6 (2), 12, 18 (2), 19, 26 & 30; February 9, 10, 13 (2), 21 & 23 (2), 2006.

We also acknowledge receipt of your submission dated February 23, 2006. This submission was not reviewed for this action. You may incorporate this submission by specific reference as part of your complete response to this action letter.

We have completed our review of this application, as amended, and it is approvable. Before the application may be approved, you will need to supply information to show what clinical events accompanied investigator's decisions to institute rescue therapy when they did not check off specific criteria. (Your submission of February 23, 2006 may address this deficiency.) We will also need to reach agreement on labeling.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request an informal meeting or telephone conference with the Division of Cardiovascular and Renal Products to discuss what steps need to be taken before the application may be approved.

This drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, call Mr. Daryl Allis, Regulatory Project Manager, at (301) 796-1034.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

Norman Stockbridge
3/1/2006 05:40:54 PM