CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-903

APPROVAL 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 February 23; March 1, 8, 14, & 16; and April 7, 2006.

The April 7, 2006 submission constituted a complete response to our March 1, 2006 action letter.

This new drug application provides for the use of NeoProfen® (ibuprofen lysine) 10 mg/mL IV Injection for closure of a clinically significant patent ductus arteriosus in premature infants weighing between 500 and 1500 g, who are no more than 32 weeks gestational age when usual medical management (e.g., fluid restriction, diuretics, respiratory support, etc.) is ineffective.

We have completed our review of this application, as amended. It 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 April 7, 2006, and immediate vial and carton labels submitted March 14, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-903**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that this application has been granted orphan drug designation, and therefore, is exempt from all requirements set forth under the Pediatric Research Equity Act of 2003.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Cardiovascular and Renal Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

Please submit one market package of the drug product when it is available.

Please note the following regarding the drug substance retest date and the drug product expiration date:

- A retest date of [redacted] is recommended for the drug substance when stored at controlled room temperature.
- An expiration date of 24 months is granted for the drug product when stored at controlled room temperature (20 – 25°C with excursions permitted to 15 – 30°C), protected from light.

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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, please 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

Enclosure: Agreed upon labeling text

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
4/13/2006 10:56:43 AM