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A SOBEL COMPANY

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November 23, 2004

Gary Buehler, Director
Office of Generic Drugs, HFD-600
CDER/FDA
Metro Park North II
7500 Standish Place
Rockville, MD 20855

Re: Docket No. 02P-0473/CP1 Naproxen Sodium Capsules, 220 mg

Dear Mr. Buehler:

Banner Pharmacaps Inc., is hereby submitting an amendment to the pediatric waiver filed on February 18, 2004, (a copy of the cover letter is enclosed for your reference as **Attachment 1**), to further support our original request for a full waiver of the pediatric study requirement for our proposed OTC product, Naproxen Sodium Capsules, 220 mg.

In accordance with the Pediatric Research Equity Act of 2003, Banner stated that its proposed product, Naproxen Sodium Capsules, 220 mg, does not provide meaningful therapeutic benefit over existing therapies. Banner's original waiver included references to several OTC pain medications other than Naproxen Sodium that are labeled for children. In this amendment, Banner is providing information to demonstrate that the active moiety, Naproxen Sodium, has already been studied in pediatric populations.

Banner respectfully requests that FDA consider the pediatric studies performed by Roche in approval of NDA 18-965 for Naprosyn® Suspension and for NDA 17-581, Naprosyn® Tablets. The FDA approved package insert for the prescription product Naprosyn® provides Clinical Pharmacology and Indications for pediatric patients aged 5 to 16 years. Roche's current package insert, approved by FDA on 11/10/2004, is enclosed for your reference as **Attachment 2**. As indicated in the Naprosyn® labeling, the oral suspension is the recommended pediatric dosage form in order to obtain the maximum dosage flexibility based on the patient's weight. Banner's proposed OTC product is only available in a single strength solid oral dosage form, which does not allow the dosing flexibility recommended for pediatric patients.

02P-0473 AMD 2

For additional consideration, Banner is providing a journal article entitled, "Pharmacokinetics and Metabolism of Naproxen in Children", by Kaufmann, et al, *Developmental Pharmacology and Therapeutics*, 1982, enclosed as **Attachment 3**.

It was noted in our original waiver request that several OTC pain relievers/fever reducers, such as Aspirin, Acetaminophen and Ibuprofen, are available in oral suspensions for pediatric use. Naproxen Sodium is available in a prescription suspension dosage form and labeled for pediatric use. In Banner's opinion, if the FDA had found the OTC solid oral dosage form of Naproxen Sodium to be safe and effective for children under age 12, then the innovator product Aleve®, NDA 20-204, would have reflected the pediatric labeling upon switch from prescription to OTC in 1994.

Banner reiterates that further pediatric studies for OTC Naproxen Sodium constitute unnecessary medical research in this special population due to the availability of other OTC pain reliever/fever reducers for children and the availability of prescription Naproxen Sodium for juvenile arthritis and pain management, for which pediatric studies were reviewed by the Agency.

To facilitate review of this information, Banner is providing six (6) desk copies for distribution within the Agency.

We trust that the information provided will allow FDA to render a decision regarding Banner's pediatric waiver request and the suitability petition to allow submission of our proposed Naproxen Sodium Capsules, 220 mg, as an ANDA. If you have any questions or require any additional information, please feel free to contact me at (336) 812-8700, extension 3312.

Sincerely,

Shelly K. Meachum

Shelly K. Meachum, B.Sc., RAC
Director, Regulatory Affairs

Courtesy copy: Cecelia Parise, Special Assistant, OGD
Attachments