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Kleinfeld, Kaplan and Becker
Attention: Richard S. Morey
1140 Nineteenth St., N.W.
Washington, D.C. 20036-6606

Docket No. 02P-0233/CP1

Dear Mr. Morey:

This letter is in reference to your petition for Hydrocodone Bitartrate and Acetaminophen Orally Disintegrating Tablets, 5 mg/500 mg, approved on February 5, 2003. For your information, a waiver of the requirement for pediatric studies under PREA has been granted for this specific drug product. Therefore, the approval of your petition is re-instated.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new dosage forms, new indications, new routes of administration and new dosing regimens contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. PREA applies retroactively to applications submitted on or after April 1, 1999. Your petition is affected by this Act because it is an ANDA suitability petition that was approved for a change in dosage form and was submitted on or after April 1, 1999.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

2003P-0233

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