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March 23, 2004

Gary Buehler, Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration, HFD-600
7500 Standish Place
Rockville, MD 20855-2773

Docket Number 03P-0365/CP 1

Dear Gary Buehler:

In response to your letter of February 3, 2004 concerning this petition and the requirements of PREA, we request a full waiver regarding Pediatric studies.

Sincerely,



Robert A. Jerussi, Ph.D.

2003P-0365

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