DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 3 2004

Jerussi Consulting, Inc.
Attention: Robert A. Jerussi, Ph.D.
3311 Midland Road
Fairfax, Virginia 22031

Docket No. 03P-0365/CP1

Dear Dr. Jerussi:

This letter is to inform you that the review of your petition may not continue until it can be determined whether the requirement for pediatric studies may be waived.

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 indications, new dosage forms, or new routes of administration include an assessment of the safety and effectiveness of the drug for the claimed indication in all relevant pediatric subpopulations unless the requirement is waived or deferred. Your pending ANDA suitability petition is affected by this Act because it is a petition for a change in active ingredient. If the change proposed in an ANDA suitability petition does not qualify for a full waiver of the pediatric studies, that petition will be denied because, under PREA, clinical studies are required to demonstrate the safety and or effectiveness of the change (Section 505(j)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act).

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of section 2 of PREA as an amendment to your ANDA suitability petition.

If you have any questions regarding these requirements, please contact Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 301-827-5845.

Sincerely,

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

2003P-0365

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