DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB - 3 2004

Kirkpatrick & Lockhart LLP
Attention: Michael H. Hinckle
1800 Massachusetts Ave. N.W., Second Floor
Washington, D.C. 20036-1221

Docket No. 02P-0226/CP1

Dear Mr. Hinckle:

This letter is to inform you that the approval of your suitability petition for Methotrexate Sodium Oral Solution, 5 mg/mL, is hereby suspended.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain an assessment of the safety and effectiveness of the drug for the claimed indication in relevant pediatric subpopulations unless the requirement is waived or deferred. Your approved ANDA suitability petition is affected by this Act because it is a petition for a change in dosage form. PREA applies retroactively to all suitability petitions submitted on or after April 1, 1999, and affects suitability petitions already approved as well as those currently pending or not yet submitted. If the change proposed in an ANDA suitability petition does not qualify for a full waiver of the pediatric studies, the approval of that petition will be revoked 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 the PREA as an amendment to your ANDA suitability petition. The approval of this petition may be reinstated if a full waiver of the pediatric study requirement is granted.

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

02P-0226

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