



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 9 2005

Charles J. Raubicheck
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151

Re: Docket No. 2004P-0070/CP2

Dear Mr. Raubicheck:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on August 17, 2004, on behalf of Watson Pharma, Inc. Your petition requests that the Agency refrain from approving any generic versions of Ferrlecit (sodium ferric gluconate complex in sucrose) until the FDA establishes guidelines for determining whether a generic sodium ferric gluconate complex product is the same active complex as Ferrlecit.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0070

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