



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 5 2004

David Zuchero, M.S., J.D.
Chesapeake Regulatory Group, Inc.
6574 River Clyde Drive
Highland, Maryland 20777

Re: Docket No. 2004P-0070/CP1

Dear Dr. Zuchero:

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 February 13, 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 certain conditions are satisfied.

FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. 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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