



NDA 20-955/S-005

Watson Laboratories, Inc.
Attention: Dorothy A. Frank, MS., R.A.C.
Executive Director, Regulatory Affairs
Research Park, 417 Wakara Way
Salt Lake City, UT 84108

Dear Ms. Frank:

Please refer to your supplemental new drug application dated December 10, 2001, received December 11, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ferrlecit® (sodium ferric gluconate complex in sucrose injection).

This "Changes Being Effected in 30 days" supplemental new drug application provides for: (1) revising the route of administration to read "For Intravenous use" on the carton, foil, and ampule labels; (2) revising the CLINICAL STUDIES and HOW SUPPLIED sections of the package insert as requested in the September 26, 2001 Agency letter.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on December 10, 2001. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Brian Strongin, R.Ph., M.B.A. at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal & Coagulation Drug
Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Joyce Korvick
6/7/02 04:23:00 PM
for Victor Raczkowski