DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-955/S-010

Watson Laboratories, Inc.
Attention: Kevin Barber, Ph.D., RAC, PMP
577 Chipeta Way
Salt Lake City, Utah 84108

Dear Dr. Barber:

Please refer to your supplemental new drug application dated December 29, 2004, received December 30, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ferrlecit® (Sodium Ferric Gluconate Complex in Sucrose) Injection.

We acknowledge receipt of your submissions dated March 31, and September 29, 2006.

Your submission of March 31, 2006 constituted a complete response to our February 22, 2006 action letter.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on September 29, 2006. The final printed labeling (FPL) must be identical, to the enclosed labeling and the submitted labeling (package insert submitted September 29, 2006).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-955/S-010**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Hyon-Zu Lee, Pharm. D., Regulatory Project Manager, at 301-796-2050.

Sincerely,

{See appended electronic signature page}

George Q. Mills, M.D., M.B.A.
Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

George Mills

10/2/2006 04:39:43 PM