DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-955/S-003

R & D Laboratories, Inc.
Attention: Jur Strobos, M.D.
Vice President, Clinical and Regulatory Affairs
4640 Admiralty Way, Suite 710
Marina del Rey, CA 90292

Dear Dr. Strobos:

Please refer to your supplemental new drug application dated August 2, 2000, received August 2, 2000, 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 August 2, September 13, October 5, October 12, October 20, October 27, November 3, November 22, December 7, December 11, 2000 and January 3, January 22, January 24, January 25, and January 30, 2001.

This supplemental new drug application provides for changes to the following sections of the approved package insert: DESCRIPTION, CLINICAL PHARMACOLOGY, CLINICAL STUDIES, WARNINGS, ADVERSE REACTIONS, OVERDOSAGE, AND DOSAGE AND ADMINISTRATION.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-955/S-003." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42

Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

Please submit one market package of the drug product when it is available.

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, Project Manager, at (301) 827-7310.

Sincerely,

{See appended electronic signature page}

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure