DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 16-267/S-034

Novartis Pharmaceuticals Corporation
Attention: Bob Miranda
59 Route 10
East Hanover, NJ 07936-1080

Dear Mr. Miranda:

Please refer to your supplemental new drug application dated March 15, 1999, received March 16, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desferal (deferoxamine mesylate, USP) Injection.

We acknowledge receipt of your submission dated December 13, 2000. Your submission of December 13, 2000 constituted a complete response to our March 10, 2000 action letter.

This "Changes Being Effected" supplemental new drug application provides for S-034 provides for revisions to the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, DOSAGE AND ADMINISTRATION, and HOW SUPPLIED sections of the package insert and revisions to the carton text.

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 submitted final printed labeling (package insert submitted December 13, 2000, immediate container and carton labels submitted December 13, 2000. Accordingly, the supplemental 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 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

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 Alice Kacuba, R.N., MSN, RAC, Regulatory Health Project Manager, at (301) 827-1602 or (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

/s/

Lilia Talarico
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