DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-267/S-044

Novartis Pharmaceuticals Corporation
Attention: Harinder Dhillon, Pharm.D.
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Dhillon:

Please refer to your supplemental new drug application dated May 9, 2005, received May 13, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Desferal® (deferoxamine mesylate, USP) Injection.

We acknowledge receipt of your submissions dated October 26, 2006 and January 16, 2007.

Your submission of January 16, 2007 constituted a complete response to our November 10, 2005 action letter.

This supplemental new drug application provides for revisions in the "Geriatric Use" subsection of the PRECAUTIONS section and the DOSAGE AND ADMINISTRATION section.

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 and with editorial revisions listed below and indicated in the enclosed labeling.

In the DOSAGE AND ADMINISTRATION section, Acute Iron Intoxication subsection, *Intravenous Administration* sub-subsection, in the second paragraph that begins with "The reconstituted solution is added to physiologic saline (e.g., 09% sodium chloride,....)" the "09% sodium chloride" should read "0.9% sodium chloride".

The final printed labeling (FPL) must be identical, and include the editorial revision indicated, to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted January 16, 2007).

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 16-267/S-044**." 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/

Rafel Rieves

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