



NDA 16-267/S-047

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Joseph Quintavalla, Ph.D.
Associate Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Quintavalla:

Please refer to your Supplemental New Drug Application (sNDA) dated March 10, 2010, received March 10, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Desferal[®] (deferoxamine mesylate, USP) Injection.

We acknowledge receipt of your amendments dated August 26 and September 2, 2010.

This "Prior Approval" supplemental new drug application provides for additions of renal failure in the WARNINGS section and hepatic dysfunction in the ADVERSE REACTIONS section.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an

action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 301-796-2192.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.
Acting Director
Division of Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure:

Application
Type/Number

Submission
Type/Number

Submitter Name

Product Name

NDA-16267

SUPPL-47

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/s/

ANN T FARRELL

09/07/2010