DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-882/S-010 **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation
Attention: Lincy Thomas, Pharm.D.
Director, Drug Regulatory Affairs
One Health Plaza
East Hanover, NJ 07936-1080

Dear Dr. Thomas:

Please refer to your supplemental new drug application dated July 31, 2009, received July 31, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Exjade® (deferasirox) Tablets for Oral Suspension.

We acknowledge receipt of your submissions dated October 9, November 6, December 23, 2009; January 13, 22, 27 and 28, 2010.

This "Prior Approval" supplemental new drug application provides for the addition of the Boxed Warning and revisions to the Indications and Usage, Dosage and Administration, Contraindications, Warnings and Precautions, Adverse Reactions, Drug Interactions, Use in Specific Populations and Clinical Pharmacology sections of the label.

CONTENT OF LABELING

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 21-882/S-010.

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, Regulatory Health Project Manager, at (301) 796-2192.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Director
Division of Medical Imaging and 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-21882	SUPPL-10	NOVARTIS PHARMACEUTICALS CORP	EXJADE (DEFERASIRIX)

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

/s/

RAFEL D RIEVES
01/28/2010