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Approval Package for:

APPLICATION NUMBER:

021825Orig1s000

Trade Name:	**Ferriprox® 500 mg Tablet**
Generic Name:	**deferiprone**
Sponsor:	**ApoPharma, Inc.**
Approval Date:	**October 14, 2011**
Indications:	Treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate

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APPLICATION NUMBER:

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021825

ACCELERATED APPROVAL

Cato Research
Attention: Lynda Sutton
U.S. Agent for ApoPharma, Inc
4364 South Alston Avenue
Durham, NC 27713-2220

Dear Ms. Sutton:

Please refer to your New Drug Application (NDA) dated January 29, 2009, received January 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ferriprox® (deferiprone) 500 mg Tablet.

We acknowledge receipt of your amendments dated February 25; April 14, 29; May 6 and 10; June 7, 14, and 22; July 11, 25, and 27; August 12, 19, 22, and 26; September 6, 16, 22, 26, and 29; October 3, 5, 7, 13, and 14, 2011.

The April 14, 2011 submission constituted a complete response to our November 30, 2009 action letter.

This new drug application provides for the use of Ferriprox® (deferiprone) Tablet for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

We have completed our review of this application, as amended. It is approved under the provisions of accelerated approval regulations (21 CFR 314.500), effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text and required patient labeling. Marketing of this drug product and related activities must adhere to the substance and procedures of the referenced accelerated approval regulations.

Based on the stability data provided in your application, the drug product is granted a 24-month expiry when stored at USP controlled room temperature 20-25ºC (68-77ºF); excursions permitted to 15-30ºC (59-86ºF).

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert, and Medication Guide). 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

IMMEDIATE CONTAINER LABELS

Submit the final printed container label that is identical to the immediate container label submitted on October 13, 2011 as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021825**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

ACCELERATED APPROVAL REQUIREMENTS

Products approved under the accelerated approval regulations, 21 CFR 314.510, require further adequate and well-controlled clinical trials to verify and describe clinical benefit. We remind you of your postmarketing requirement specified in your submission dated October 13, 2011.

You are required to conduct such trials with due diligence. If postmarketing trials fail to verify that clinical benefit is conferred by deferiprone, or are not conducted with due diligence, we may, following a hearing in accordance with 21 CFR 314.530(b), withdraw or modify approval.

Granting of these approvals are contingent upon completion of clinical trials to verify the clinical benefit of deferiprone. These postmarketing trials are subject to the reporting requirements of 21 CFR 314.81.

This requirement, along with required completion dates, is listed below.

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