



NDA 208030/S004

## SUPPLEMENT APPROVAL

ApoPharma  
c/o Cato Research, Ltd.  
Attention: Sheila Plant, PhD  
Director, Regulatory Strategy  
4364 South Alston Avenue  
Durham, NC 27713-2220

Dear Dr. Plant:

Please refer to your supplemental new drug application (sNDA) dated and received August 30, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ferriprox (deferiprone), Oral Solution, 80 mg/mL and 100 mg/mL

This Prior Approval supplemental new drug application provides for updates to the labeling to comply with the Pregnancy and Lactation Labeling Rule (PLLR).

### **APPROVAL & 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.

### **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 FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, Medication Guide, and Instructions for Use, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

## **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 Charlene Wheeler, Acting Chief, Project Management Staff, at 301-796-1141.

Sincerely,

*{See appended electronic signature page}*

Albert Deisseroth, MD, PhD  
Associate Director  
Division of Hematology Products  
Office of New Drugs  
Center for Drug Evaluation and Research

### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information (2)
  - Medication Guide (2)
  - Instructions for Use (2)

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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ALBERT B DEISSEROTH  
02/20/2020 10:35:46 AM