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APPLICATION NUMBER:

212269Orig1s000

SUMMARY REVIEW

Summary Review for Regulatory Action

Date	May 18, 2020
From	Albert Deisseroth MD, PhD, Associate Division Director
Subject	Division Director Summary Review
NDA #/Supplement#	NDA 212269
Applicant	ApoPharma
Date of Submission	July 19, 2019
PDUFA Goal Date	May 19, 2020
Proprietary Name/Proper Name	Ferriprox (twice daily)/Deferiprone
Dosage Forms	1000 mg tablet given twice daily
Recommendation	Approval
Recommended Indication	Treatment of patients with transfusional iron overload due to Thalassemia Syndromes when current chelation therapy is inadequate .

Material Reviewed/Consulted	
Medical Officer Review	Andrew Dmytrijuk/Kathy Robie Suh
Associate Director for Labeling	Virginia Kwitkowski
Clinical Pharmacology	Oluseyi Adeniyi

Summary Review for Regulatory Action:

(This review was derived in part from the reviews of Drs. Andrew Dmytrijuk, Oluseyi Adeniyi and Kathy Robie-Suh.)

On July 19, 2019, ApoPharma submitted NDA 212269 to the FDA requesting approval as a new formulation of deferiprone (Ferriprox) (b) (4) 1000 mg tablet to reduce the pill burden for patients and to increase the convenience by changing from the previously approved three times a day 1000 mg tablet to the proposed twice a day schedule for the new tablet.

This request was supported by study LA45-0116 which was entitled "Comparison of the pharmacokinetics and safety of multiple doses of deferiprone twice daily (Ferriprox (twice daily)) tablets in healthy volunteers". This study which enrolled 36 volunteers, was designed to be a bioequivalence study in which the Ferriprox (twice daily) was to be compared to the approved Ferriprox (three times daily) tablets. The result was that the 90% confidence intervals of the ratios of the PK parameters AUC0-t, AUCinf, and Cmax for Ferriprox (twice daily)/Ferriprox (three times daily) in serum were within the 0.8-1.25 bioequivalence range. On the basis of this finding, it was concluded that the Ferriprox (twice daily) formulation and the marketed Ferriprox (three times daily) formulation are bioequivalent. All adverse events in this study were mild to moderate.

Dr. Oluseyi Adeniyi of Clinical Pharmacology reported that in study LA53-0116, (b) (4) (b) (4) the Ferriprox (twice daily) tablet as compared to the Ferriprox (three times daily) tablet, (b) (4) (b) (4) for the Ferriiprox (twice daily) may be misleading (see the review of Dr. Adeniyi for details). Therefore, it was decided to approve the request for the twice daily schedule for the new 1000 mg tablet (b) (4) (b) (4) Furthermore, in order to avoid confusion between the two 1000 mg tablets, it was decided to call the new twice daily formulation Ferriprox (twice daily) and to refer to the already marketed 1000 mg tablet as Ferriprox (three times daily).

Recommended Regulatory Action of the Supervisory Associate Division Director: This reviewer agrees with the recommendation of the review teams for approval of the new 100 mg formulation with the following designation: Ferriprox (twice daily).

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/s/

ALBERT B DEISSEROTH
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