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APPLICATION NUMBER:

021825Orig1s000

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	October 21, 2009
To:	Rafel (Dwaine) Rieves, MD, Director Division of Medical Imaging and Hematological Products (DMIHP)
Thru:	Claudia Karwoski, Pharm.D., Director Division of Risk Management (DRISK) Office of Surveillance and Epidemiology (OSE)
From:	OSE DRISK REMS Review Team: Mary Dempsey, Risk Management Program Coordinator, DRISK Suzanne Berkman Robottom, Pharm.D, Risk Analyst Team Leader, DRISK Joyce Weaver, Pharm.D., Senior Drug Risk Management Analyst, DRISK, Scientific Lead
Subject:	Review of Risk Evaluation and Mitigation Strategy (REMS)
Drug Name(s):	Ferriprox (deferiprone)
Submission Number:	0024
Application Type/Number:	NDA 21-825
Applicant/sponsor:	Apopharma
OSE RCM #:	2009-354

We acknowledge the Sponsor's July 9, 2009 proposed Risk Evaluation and Mitigation Strategy (REMS) for Ferriprox (deferiprone). Due to deficiencies in the Ferriprox application, the Division of Medical Imaging and Hematological Products (DMIHP) plans to issue a Complete Response (CR) letter for this review cycle.

At this time, we will defer comment on the Sponsor's proposed REMS. A final review on the appropriate risk management strategy for deferiprone will be provided after the Sponsor responds to the deficiencies in the CR letter and the risk-benefit profile can be re-evaluated. We note that a tentative decision was made within the Agency regarding the risk mitigation strategy necessary to mitigate the risk of deferiprone-induced agranulocytosis. The Sponsor was notified in a telephone conference on August 12, 2009 that a REMS with Elements to Assure Safe Use (ETASU) to ensure monitoring of blood

counts would likely be needed. On October 14, 2009, the Sponsor submitted a proposed REMS incorporating this advice. Because this REMS proposal was submitted so close to the November 30 goal date for the application, we will not review the submission in this cycle. We suggest that the CR letter include the following paragraph after the description of the deficiencies in the application.

"Depending on the outcome of these analyses, FDA may require the submission of a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drug outweigh its risks. In your response to this letter, you may wish to resubmit the REMS submitted October 14, 2009."

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/s/

JOYCE P WEAVER
10/22/2009

CLAUDIA B KARWOSKI
10/22/2009
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