

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208030Orig1s000

ENVIRONMENTAL ASSESSMENT

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: August 19, 2015

FROM: Donghao (Robert) Lu, Ph.D.
Division of Pre-Marketing Assessment - I
Office of New Drug Products

TO: File NDA 208030

SUBJECT: Environmental assessment

RECOMMENDATION: The environmental assessment for NDA 208030 is acceptable.

REVIEW NOTE:

Ferriprox® (deferiprone) 100 mg/mL oral solution is an alternative dosage form of deferiprone for patients who have difficulty swallowing Ferriprox (deferiprone) 500 mg tablets. Based on the condition of 21 CFR 25.31(b) for action on a New Drug Application regarding the increase of the use of an active moiety, where the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion (ppb), ApoPharma Inc. is claiming a categorical exclusion from environmental assessment for NDA 208030 (Ferriprox® (deferiprone) 100 mg/mL oral solution).

In support of this claim, ApoPharma Inc. made a calculation of the ‘worst case’ scenario for the use of deferiprone in US patients with transfusional iron overload due to thalassemia syndromes in the US. The calculation is acceptable.

ApoPharma Inc. states that “to the best of our knowledge, no extraordinary circumstances exist that would cause deferiprone to be a special hazard at the calculated environmental concentration, which is <1 ppb, and supports the claim for categorical exclusion from environmental assessment” as per 21 CFR 25.31(b).

Donghao R. Lu -S

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