CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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PROPRIETARY NAME 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
Office of Medication Error Prevention and Risk Management

Proprietary Name Review

Date:	July 28, 2011
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Drug Name(s):	Ferriprox (Deferiprone) Tablets 500 mg
Application Type/Number:	NDA 021825
Applicant:	ApoPharma
OSE RCM #:	2011-1398

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Ferriprox (Deferiprone), from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

1.1 REGULATORY HISTORY

DMEPA initially reviewed the name Ferriprox in OSE Review 2006-169, dated January 30, 2007, and found the name unacceptable due to concerns that the name was misleading because the "Ferr" portion of the name may imply that Ferriprox is an iron supplement. The name was later resubmitted for reconsideration and re-evaluated in the September 3, 2009 OSE Review 2009-1153. The Applicant stated there would be a Risk Evaluation and Mitigation Strategy (REMS) with restricted distribution plan in place prior to marketing the product and this information was considered in our re-evaluation of the name. DMEPA found the name acceptable in OSE Review 2009-1153 based on this information. A Complete Response action was taken on November 30, 2009. The Applicant submitted a Class 2 resubmission and Request for Review of a Proprietary Name which were received on April 13, 2011 and April 29, 2011, respectively. No REMS was submitted during this cycle.

Ferriprox is currently marketed in multiple countries outside the United States. Additionally, Ferriprox is an Orphan Drug.

1.2 PRODUCT INFORMATION

Ferriprox is an iron chelator indicated for the treatment of patients with transfusional iron overload when current chelation therapy is inadequate. The recommended dosage is 25 mg/kg to 33 mg/kg body weight, orally, three times a day for a total daily dose of 75 mg/kg to (b) (4) mg/kg body weight. The recommended initial total daily dose of Ferriprox is 75 mg/kg body weight. The dose should be rounded to the nearest ½ tablet. Ferriprox is a scored tablet and breakable in half. It will be supplied in 100-count bottles.

Ferriprox has a boxed warning concerning agranulocytosis and neutropenia. The Agency has not yet determined whether a REMS and/or restricted distribution plan will be required for this product.

2 RESULTS

The following sections provide the information obtained and considered in the evaluation of the proposed proprietary name.

2.1 PROMOTIONAL ASSESSMENT

DDMAC determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Hematology Products concurred with the findings of DDMAC's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects of the name were considered in the overall evaluation.

2.2.1 United States Adopted Names (USAN) SEARCH

The United States Adopted Name (USAN) stem search conducted on July 15, 2011, identified that a USAN stem is not present in the proposed proprietary name.

2.2.2 Components of the Proposed Proprietary Name

The proposed name Ferriprox is misleading due to the "Ferr" prefix in the name which may imply that Ferriprox is an iron supplement product when, in fact, it is a product used to treat iron overload. Although "fer-" and "ferr-" are not USAN stems, there are multiple prescription and non-prescription iron-containing products on the market that begin with these letters, for example, Ferrlecit, Fergon, Feratab, and Fer-In-Sol, to name a few. All of the aforementioned products are iron supplements. Additionally, there are two currently available iron chelators, Desferal (deferoxamine mesylate) and Exjade (deferasirox). Neither of these proprietary names begin with "Fer" or "Ferr". Because the name Ferriprox strongly suggests that the product is an iron supplement when in fact it is indicated as a treatment for iron overload, DMEPA believes that confusion can ensue regarding the product's suggested versus its actual indication.

2.2.3 FDA Adverse Event Reporting System (AERS) Selection of Cases

Ferriprox is currently marketed in countries throughout Europe, Asia, Africa, South America and elsewhere. Therefore, DMEPA searched the Adverse Event Reporting System (AERS) database on June 3, 2011 using the MedDRA High Level Group Terms "Medication Errors" and "Product Quality Issues", active ingredient "Deferiprone", trade name "Ferriprox", and verbatim "Ferr%" and "Defer%".

The reports were manually reviewed to determine if a medication error occurred. Duplicate reports were combined into cases. Cases that described a medication error were categorized by type of error. We reviewed the cases within each category to identify factors that contributed to the medication errors. If the root cause(s) were associated with name confusion involving Ferriprox, the cases were considered pertinent to this review. Those cases that did not describe a medication error or did not describe an error applicable to this review were excluded from further analysis.

The search yielded one foreign case from Greece (ISR #5523063) which described a chelation overdose involving Ferriprox and another agent. Thus, this case does not inform this review and will not be discussed further.

2.2.4 FDA Name Simulation Studies

Twenty-nine practitioners participated in DMEPA's prescription studies. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines

In response to the OSE email dated May 12, 2011, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed name at the initial phase of the name review.

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