

FDA Issues Warning Letter on AMAG Webpages

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Summary: The FDA has released a warning letter to AMAG Pharmaceuticals for failing to include appropriate risk information and accurate product claims on webpages for its GastroMARK[®] and Feraheme[®] products. Although each page includes a link to the full package inserts, this does not adequately fulfill fair balance requirements. Drug companies can avoid this in the future by ensuring that all risk information is presented alongside product claims, and by submitting all promotional material to DDMAC before publication.

Key Information

In October 2010, the Food and Drug Administration (FDA) issued a warning letter to AMAG Pharmaceuticals for the GastroMARK and Feraheme product pages located on the main AMAG website. GastroMARK is an oral drug for patients undergoing magnetic resonance imaging (MRI); it is meant to enhance the delineation of the bowel to distinguish it from adjacent organs and tissues in the gastrointestinal tract. Side effects include abdominal pain, diarrhea, nausea and vomiting. Feraheme is an injectable that has been indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease. Risks include anaphylaxis and/or anaphylactoid reactions, hypotension and iron overload. Feraheme may also affect the accuracy of MRI.

The FDA has cited both webpages for omission of risk information and for broadening the indication for GastroMARK. The webpages for both drugs list numerous efficacy claims, but fail to present adequate information about risks or side effects—for example, the site fails to mention that GastroMARK is contraindicated for patients with intestinal obstruction or perforation. The GastroMARK webpage also fails to present the complete indication, because it does not mention GastroMARK is indicated only for adults. The Feraheme webpage lists approved product indication claims, such as the treatment of iron deficiency anemia in patients with chronic kidney disease, alongside claims that have not been approved by the FDA, such as the treatment of anemia in patients with abnormal uterine bleeding, cancer or gastrointestinal diseases, and the use of Feraheme as a diagnostic agent for MRIs in patients with peripheral arterial disease. Both product pages included a downloadable package insert, but neither included the Important Safety Information.

The warning letter notes that both webpages provide links to download the package inserts for each drug; the pages also provide links to the main websites for Feraheme and GastroMARK. However, these links are buried within the pages and providing these links does not adequately mitigate the omission of risk information from both pages. Furthermore, AMAG failed to submit both webpages to DDMAC before initial publication, as required by 21 CFR 314.81(b)(3)(i).

Implications and Action Items

Although AMAG Pharmaceuticals did include a link to the package insert for each product, the FDA does not consider this an adequate adherence to fair balance laws. Drug companies can avoid similar FDA warnings by taking the following actions:

- **Ensure** that risk information is presented on corporate product webpages as well as individual product websites and is given the same weight as efficacy claims.
- **Distinguish** between FDA-approved usages for the drug and product claims that are still in the approval process.
- **Submit** an FDA-2253 form to DDMAC before publication for all webpages that include product information and could be considered promotional material.

For more information on the warning letters and to see a copy of the promotional material, visit the FDA's website at: <http://bit.ly/8z97kM>

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