

AMAG iron replacement drug's Canadian approval stalled

Mass High Tech: The Journal of New England Technology

Health Canada has stalled a new drug submission from AMAG Pharmaceuticals Inc. with a notice of non-compliance for its Feraheme injection, intended to treat iron deficiency anemia in adult chronic kidney disease patients. The treatment was subjected to scrutiny in the U.S. – and a demand for [new warning labels](#) [1] – by the FDA in 2010 following reports of life-threatening hypersensitivity to the drug and instances of significant low blood pressure.

Lexington-based AMAG and Takeda Canada Inc., its commercial partner, have 90 days to respond to the notice.

[SOURCE](#) [2]

Source URL (retrieved on 01/30/2015 - 1:11am):

<http://www.mdtmag.com/news/2011/02/amag-iron-replacement-drugs-canadian-approval-stalled>

Links:

[1] <http://www.masshightech.com/stories/2010/11/29/daily12-AMAG-avoids-FDA-black-box-warning.html>

[2] <http://www.masshightech.com/stories/2011/02/07/daily40-AMAG-iron-replacement-drugs-Canadian-approval-stalled.html>