



IrvineScientific®

1830 East Warner Avenue
Santa Ana, CA 92705-5505
800 437 5706 | 949 261 7800 | Fax: 949 261 6522
www.irvinesci.com

January 29, 2018

TO WHOM IT MAY CONCERN:

Recently a manufacturer of Gentamicin Sulfate released batches with elevated levels of histamine. These batches of Gentamicin Sulfate were then used by various IVF manufacturers to produce final products. On October 31, 2017 the Medicines and Healthcare Products Regulatory Agency (MHRA) contacted Irvine Scientific and inquired about these Gentamicin Sulfate lots that contained high histamine levels, their request included the affected batches.

The affected Gentamicin Sulfate lots were not received by Irvine Scientific, thus Irvine Scientific products were not affected by this notification.

As a precautionary measurement, Irvine Scientific tested raw material inventory lots of Gentamicin Sulfate received from the supplier and found them to be under the acceptable histamine levels.

Further preventive measures proactively taken by Irvine Scientific included testing incoming lots of Gentamicin Sulfate for the presence of histamine. Additionally, our supplier confirmed they now test histamine residues as part of their acceptance criteria. With the implementation of testing for histamine residue by the supplier along with the set specification and incoming testing Irvine Scientific has mitigated the risk of accepting higher than normal levels of histamine lots.

If you have any questions in regards to the information that we have provided please feel free to contact me by email at mlf@irvinesci.com, phone at 949-261-7800 extension X 288.

Warm regards,

Marlin Frechette
Director for Quality Systems and Regulatory Affairs