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November 19, 2013

Dear Valued Customer,

Sigma-Aldrich is aware that pharmaceutical customers are assessing raw materials to gauge their compliance risk as it applies to elemental (metal) impurities. With the recent deferral of USP General Chapters <232> and <233>, and the fact that ICH Q3D was revised in July and released for comment, the only remaining guidance is EU's Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents. EU has indicated that they will delay the application of this on existing drugs, so it is only applicable to new drugs.

As required in the EU guidance, Sigma-Aldrich will work with our customers to provide information on metal catalysts and metal impurities used in the production of materials designated for sale as API's or Excipients used in new drugs. Sigma-Aldrich will also provide information in product dossiers on products designated as Pharmagrade. Information may also be available on other products with an EQP status of Elite or GMP. This information should be requested from your SAFC Sales Representative.

We continue to stand behind any Heavy Metals results that are on our current specification or other existing documentation. We are also working to evaluate the impact of the draft ICH Q3D on our products. Please contact your SAFC Sales Representative if you have any further questions.

Sincerely,

Patty Benson

Patty Benson
Director, Quality Operations SAFC-US