

Press Release

Matthias Link
Corporate Communications

Fresenius SE & Co. KGaA
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
T +49 6172 608-2872
F +49 6172 608-2294
Matthias.Link@fresenius.com
www.fresenius.com

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Fresenius Kabi receives FDA Warning Letter for Kalyani

Fresenius Kabi received a Warning Letter, dated July 1, from the U.S. Food and Drug Administration (FDA) related to an inspection of its oncolytic API plant in Kalyani, India in January 2013. As a precautionary measure, production at the plant had been put on hold in January 2013. Fresenius previously informed about this inspection in February 2013.

The Warning Letter observations are related to GMP non-conformities regarding manufacturing, documentation practices and data integrity. Many of the data integrity items cited in the Warning Letter were self-identified by Fresenius Kabi post-inspection and shared with the FDA.

The company has made significant progress in remedying the issues cited in the Warning Letter. Based on a detailed remediation action plan submitted to the FDA, Fresenius Kabi has begun the process of restarting manufacture at the facility.

The company takes this matter very seriously and intends to comprehensively respond in a timely manner to the Warning Letter. Fresenius Kabi fully confirms its 2013 guidance which includes expected one-time charges to remediate the issues.

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About Fresenius

Fresenius is a health care group with international operations, providing products and services for dialysis, hospital and outpatient medical care. In 2012, Group sales were €19.3 billion. On March 31, 2013, the Fresenius Group had 171,764 employees worldwide.

For more information visit www.fresenius.com.

This release contains forward-looking statements that are subject to various risks and uncertainties. Future results could differ materially from those described in these forward-looking statements due to certain factors, e.g. changes in business, economic and competitive conditions, regulatory reforms, results of clinical trials, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. Fresenius does not undertake any responsibility to update the forward-looking statements in this release.

Fresenius SE & Co. KGaA
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11852
Chairman of the Supervisory Board: Dr. Gerd Krick

General Partner: Fresenius Management SE
Registered Office: Bad Homburg, Germany
Commercial Register: Amtsgericht Bad Homburg, HRB 11673
Management Board: Dr. Ulf M. Schneider (Chairman), Dr. Francesco De Meo, Dr. Jürgen Götz, Mats Henriksson, Rice Powell, Stephan Sturm, Dr. Ernst Wastler
Chairman of the Supervisory Board: Dr. Gerd Krick