

Press Release

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Fresenius Kabi receives FDA Warning Letter for Fenwal plant in Puerto Rico

Fresenius Kabi received a Warning Letter, dated August 16, from the U.S. Food and Drug Administration (FDA) related to an April 2013 inspection of its Fenwal blood bag manufacturing plant in Maricao, Puerto Rico. Fresenius Kabi acquired Fenwal in December 2012.

The Warning Letter observations are primarily related to complaint-handling procedures, labeling issues, and filing of field alerts not in accordance with FDA regulations. The Warning Letter was not issued as a result of adverse events related to patient safety.

Following the inspection, Fresenius Kabi submitted a detailed remediation action plan to the FDA. The company has made significant progress in remedying the issues cited in the Warning Letter including improvements to its procedures and documentation. Production at the plant is continuing.

The company takes this matter very seriously and intends to respond in a timely and comprehensive manner to the Warning Letter. No material sales and earnings impact on Fresenius Kabi's business is expected. Fresenius Kabi fully confirms its 2013 guidance.

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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 June 30, 2013, the Fresenius Group had 173,325 employees worldwide.

For more information visit the Company's website at 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.

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