APP Pharmaceuticals receives FDA warning letter regarding Grand Island plant - no material financial impact expected

APP Pharmaceuticals (“APP”), a subsidiary of Fresenius Kabi, has received a warning letter dated 22 February 2012 from the New York District FDA office regarding the Company’s Grand Island plant. The warning letter follows an inspection at the facility which concluded in July 2011. The Company responded on 27 July 2011 detailing the corrective and preventative actions planned to address the Agency’s concerns, and since then has made significant progress in collaboration with the FDA in remedying these issues. In addition, the warning letter refers to the marketing status of five ‘grandfathered’ generic products with a total annual sales volume of approx. €15 million.

The Company has full confidence in the quality of the products it has distributed from the Grand Island facility and expects to continue production at the plant. We believe that the ongoing enhancement efforts can be successfully completed without disrupting output.

Both APP and Fresenius Kabi are committed to the highest standards of quality and compliance in manufacturing across its global operations. We regard our relationship with the FDA as critical to both our past and future success, and we will continue to work constructively and expeditiously with the Agency to resolve all the issues addressed in the warning letter.

APP will respond to the FDA within the required 15 working day time frame. No material sales and earnings impact on Fresenius Kabi’s U.S. business is expected, and Fresenius Kabi fully confirms its 2012 guidance.
Fresenius SE & Co. KGaA,
represented by Fresenius Management SE,
Board of Management

Bad Homburg v.d.H., February 24, 2012

End of note