

Press Release

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FDA warning letter on Dialyzer Product Documentation – no effects expected on company guidance for 2013

Fresenius Medical Care North America (FMCNA) announced today that it has received a warning letter from the Food and Drug Administration (FDA), asserting that the organization did not conduct adequate design verification studies of its electron beam (E-beam) sterilized polysulfone dialyzers manufactured at its facility located in Ogden, UT and that the process for design validation of these dialyzers has been incomplete. FMCNA received FDA clearance for this product in December 2000. The warning letter does not impose a product recall. FMCNA has continued confidence in the quality of products that are produced in Ogden.

“Fresenius Medical Care North America is committed to working with the FDA to resolve the concerns stated in the Letter,” said Rice Powell, CEO of Fresenius Medical Care. “We will address the FDA’s observations as soon as possible. We do not expect any effects on the company’s guidance in terms of revenue and earnings in 2013.”

Fresenius Medical Care is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 2.2 million individuals worldwide. Through its network of 3,160 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 257,916 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products. For more information about Fresenius Medical Care, visit the Company's website at www.fmc-ag.com.

Disclaimer

This release contains forward-looking statements that are subject to various risks and uncertainties. Actual results could differ materially from those described in these forward-looking statements due to certain factors, including changes in business, economic and competitive conditions, regulatory reforms, foreign exchange rate fluctuations, uncertainties in litigation or investigative proceedings, and the availability of financing. These and other risks and uncertainties are detailed in Fresenius Medical Care AG & Co. KGaA's reports filed with the U.S. Securities and Exchange Commission. Fresenius Medical Care AG & Co. KGaA does not undertake any responsibility to update the forward-looking statements in this release.