



Align Technology Releases Update Regarding FDA Warning Letter

SAN JOSE, Calif., Nov. 30, 2010 (GLOBE NEWSWIRE) -- Align Technology, Inc. (Nasdaq:ALGN) announced today that it received a Warning Letter from the U.S. Food and Drug Administration (FDA) on November 18, 2010 requesting additional documentation relating to written implemented corrections and corrective actions in complaint handling and Medical Device Reporting procedures taken by Align following an on-site inspection of Align's corporate headquarters in San Jose, California between June 29 and August 9, 2010. The FDA inspection resulted in the issuance of a Form 483 Notice that contained four observations.

Align submitted a written response to the Form 483 Notice on August 26 and an additional written response on November 8 that provided a full and complete update of the actions the Company has taken and plans to take to fully address the observations. On November 22, Align submitted a written response to the Warning Letter that included copies of documentation requested by the FDA. Align has requested a meeting with FDA to ensure that its November 22 response fully addresses the issues contained in the Warning Letter.

"Compliance with FDA regulations is taken very seriously at Align and this matter is receiving the highest priority within the company," said Roger E. George, Align Technology vice president and general counsel. "It appears that at the time the FDA issued the Warning Letter, it may not have fully reviewed the actions Align has completed and plans to complete to address the observations contained in the Form 483 Notice. We believe our response of November 8, 2010 may have crossed in the mail with the FDA's Warning Letter and we are working with the FDA to quickly resolve this matter with minimal impact on the Company."

The Warning Letter is posted on the FDA's website at www.fda.gov.

About Align Technology, Inc.

Align Technology designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens. Align Technology was founded in March 1997 and received FDA clearance to market Invisalign in 1998. Today, the Invisalign product family includes Invisalign, Invisalign Teen, Invisalign Assist, Invisalign Express, and Vivera Retainers.

To learn more about Invisalign or to find an Invisalign trained doctor in your area, please visit www.invisalign.com or call 1-800-INVISIBLE.

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