



Clinical Diagnostic Solutions has been issued a Notice of Inspectional Observations by FDA

Clinical Diagnostic Solutions, Inc. (CDS), a subsidiary to Boule Diagnostics AB, has been issued a Notice of Inspectional Observations (FDA Form 483) by the US Food and Drug Administration (the FDA). After a routine inspection of CDS' operations, inspectional observations were issued by the FDA regarding documentation relating to change management processes and complaints handling. CDS has engaged a well-reputed consulting firm, who employ former FDA personnel, to provide third-party independent subject matter experts with the required experience and background to support the efforts to address the observations identified by the FDA. CDS has submitted to the FDA a response that includes a corrective action plan and begun implementation. The inspectional observations do not place limitations on production or the sale of products.

Compliance with regulations is of utmost importance, and implementation of the corrective action plan has the highest priority. The Company is dedicating the required resources to this matter and will fully cooperate with the FDA to successfully resolve the observations and comply with all FDA regulations.

The FDA has previously also announced a routine inspection of the Swedish operations during the month of November.

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About Boule Diagnostics AB (publ)

Boule Diagnostics AB is a global diagnostics company that develops, manufactures and markets instruments and consumable products for blood diagnostics. The company serves hospitals, clinics, laboratories and companies within blood diagnostics, in both human and veterinary hematology. The company operates via subsidiaries in Sweden, the USA, Mexico and Russia. The company products are sold globally primarily through distributors, supported by Boule's own local sales and support personnel. The Boule shares are listed on Nasdaq Stockholm since 2011. www.boule.com

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