

Nazareth (Belgium)/Rotterdam (The Netherlands), 15 May 2026 – 7:00AM

Fagron update on FDA communication regarding the November 2025 inspection at Boston

Following the FDA's inspection of Fagron's Boston facility in November 2025, the Company received a Warning Letter from the FDA on May 12, 2026.

Production at the Boston facility continues as normal, and the Company continues to supply its customers with no material impact on the business. The Warning Letter is associated with drug products produced at the facility using IV bags supplied by a third-party manufacturer, as well as other process improvements.

For the IV bag issues, Fagron's own quality systems identified the defect trend in these supplier components and, in February 2026, out of an abundance of caution, the Company initiated a limited, voluntary, Class II recall of selected lots of drug products produced using these IV bags with no adverse events recorded. Since then, the supplier has implemented corrective actions in respect of the relevant components, and Fagron has not identified any further related defects through its incoming inspection regime. A comprehensive remediation plan is in place, and the Company will respond in full to the Warning Letter within the timeframe set out by the FDA.

Fagron's top priority is providing safe and effective sterile drug products to our customers and their patients. The Company continues to invest in the quality systems that underpin its global operations and remains close to its customers and partners to collectively raise standards across the industry.

Financial calendar

30 July 2026

Half year results 2026

8 October 2026

Trading update third quarter 2026

Results and trading updates are published at 7.00 AM CET.

Further information

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About Fagron

Fagron is the leading global company active in pharmaceutical compounding, focusing on delivering personalized medicine to hospitals, pharmacies, clinics, and patients in more than 38 countries around the world.

The Belgian company Fagron NV is based in Nazareth and is listed on Euronext Brussels and Euronext Amsterdam under the ticker symbol 'FAGR'. Fagron's operational activities are managed through the Dutch company Fagron BV with head office in Rotterdam.

Important information regarding forward-looking statements

Certain statements in this press release may be deemed to be forward-looking. Such forward-looking statements are based on current expectations and are influenced by various risks and uncertainties. Consequently, Fagron cannot provide any guarantee that such forward-looking statements will, in fact, materialize and cannot accept any obligation to update or revise any forward-looking statement as a result of new information, future events or for any other reason.



In the event of differences between the English translation and the Dutch original of this press release, the latter prevails.