



NEWS RELEASE

Aptar's N-Sorb Nitrosamine Mitigation Solution Accepted to US FDA's Emerging Technology Program

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N-Sorb leverages company's proven 3-Phase Activ-Polymer™ platform technology to address recent concerns related to N-nitrosamine impurities in pharmaceuticals

CRYSTAL LAKE, Ill.--(BUSINESS WIRE)-- AptarGroup, Inc. (NYSE: ATR), a global leader in drug and consumer product dosing, dispensing and protection technologies, announced that its N-Sorb nitrosamine mitigation solution has been accepted into the U.S. Food & Drug Administration's (FDA) Emerging Technology Program (ETP), which helps promote the adoption of innovative approaches to pharmaceutical product design and manufacturing.

Aptar's N-Sorb Nitrosamine Mitigation Solution. (Photo: Business Wire)

N-Sorb leverages Aptar CSP Technologies' proven 3-Phase

Activ-Polymer™ platform technology to address the pressing issue of N-nitrosamine impurities in pharmaceuticals. These impurities, classified as probable human carcinogens, have raised significant regulatory concerns and prompted numerous drug product recalls. Nitrosamines can form during drug product storage or transport, posing risks to patient health.

N-Sorb technology can be deployed in multiple formats by integrating active material science into polymers. For example, the technology can be incorporated into a blister format that integrates a piece of N-Sorb Activ-Film™ material into each individual Activ-Blister™ cavity. This same platform is currently trusted by global brands to protect sensitive Active Pharmaceutical Ingredients (APIs) from degradation due to moisture and oxygen exposure. Alternatively, the technology can be seamlessly integrated into a container closure system. N-Sorb's intelligent design allows it to react with nitrosamine precursors in the packaging headspace to inhibit nitrosamine formation and scavenge nitrosamine impurities post-formation.

By delivering this Generally Recognized as Safe (GRAS) material directly within the packaging, N-Sorb can eliminate the need for pharmaceutical developers to reformulate their drug products, which could support compliance with US FDA and EU EMA regulations regarding safe nitrosamine levels. The active packaging intervention represents a paradigm shift in managing impurities and degradation, which could significantly enhance overall mitigation strategies and aligns with the latest FDA guidance (updated Sept. 4, 2024) that recognizes packaging changes as a potential mitigation strategy. By addressing nitrosamine concerns with active packaging, N-Sorb technology can help accelerate drug product development and help alleviate the burden of drug shortages due to recalls.

“The FDA’s Emerging Technology Program is highly selective, reserved for the most promising pharma and healthcare sector solutions,” said Badre Hammond, VP Global Commercial Operations and GM for Aptar CSP Technologies. “Our ability to mitigate nitrosamine formation with active material science introduces a critical quality control element, designed to ensure patient safety. We are eager to collaborate with the FDA’s Emerging Technology team to empower pharma brands with this innovative offering.”

As part of the program, industry representatives meet with the FDA’s Emerging Technology Team members to discuss, identify and resolve potential technical and regulatory issues related to the development and implementation of novel technologies prior to regulatory submission. This multi-stakeholder effort aligns with the FDA’s mission to facilitate modernization in the pharmaceutical industry, reducing time and cost requirements for introducing novel solutions.

About Aptar

Aptar is a global leader in drug and consumer product dosing, dispensing and protection technologies. Aptar serves a number of attractive end markets including pharmaceutical, beauty, food, beverage, personal care and home care. Aptar CSP Technologies leverages its active material science expertise to transform ideas into market opportunities, accelerate and de-risk the product development process, and provide complete solutions that improve consumers’ and patients’ lives. The company offers a complete set of services from concept ideation, to design and engineering, to product development, global production, quality control, and regulatory support that results in expedited speed-to-market. For more information, please visit www.csptechnologies.com and www.aptar.com.

This press release contains forward-looking statements. Forward-looking statements generally can be identified by the fact that they do not relate strictly to historical or current facts and by use of words such as “expects,” “anticipates,” “believes,” “estimates,” “future,” “potential,” “continues” and other similar expressions or future or conditional verbs such as “will,” “should,” “would” and “could” are intended to identify such forward-looking statements. Forward-looking statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and are based on our beliefs as well

as assumptions made by and information currently available to us. Accordingly, our actual results or other events may differ materially from those expressed or implied in such forward-looking statements due to known or unknown risks and uncertainties that exist in our operations and business environment including, but not limited to: the successful integration of acquisitions; the regulatory environment; and competition, including technological advances. For additional information on these and other risks and uncertainties, please see our filings with the Securities and Exchange Commission, including the discussion under “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Form 10-K and Forms 10-Q. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as otherwise required by law.

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