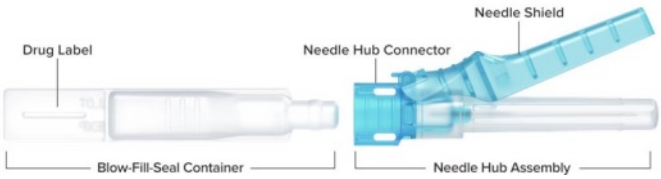
Apiject Submits Innovative Prefilled Single Dose Injection Device for FDA Approval

An Important Step Forward for the Improvement in Medical Care for Patients in the U.S. and Around the World.

STAMFORD, CT, September 25, 2025 — Today Apiject Systems, Corp. (Apiject) announced its submission for regulatory approval of its New Drug Application (NDA) to the Food and Drug Administration (FDA) for the world's first injectable medicine to use Apiject's single dose, single use prefilled plastic syringe.

Central to today's NDA submission of the drug Glycopyrrolate in the Apiject injection device is a drug delivery development platform that integrates two proven medical technologies: Blow-Fill-Seal (BFS) liquid packaging technology and precision injection molding of pen-style needle hubs. This combination enables the creation of a new category of prefilled drug delivery devices that are more scalable and affordable than traditional glass vials and prefilled syringes. The key for BFS is it is a continuous manufacturing process that operates at high-speed and relies on a single raw material that is available domestically.



All devices and prototypes shown have not been cleared by the FDA or any other regulator.

Jay Walker, Co-Founder, Executive Chairman and CEO of Apiject, said, "Today's submission is an exciting and significant step forward for Apiject. We have spent the last 5 years preparing BFS to play a central role in the future of drug delivery, because it meets the needs of the new challenges of today's healthcare realities. Our work has involved extensive drug container and device design and development, building enhancements to the manufacturing process, inventing new equipment as well as extensive end-to-end testing. The global demand for medical injections continues to grow at a double-digit pace. We need new domestic capacity, more flexibility, lower costs, and we need new thinking."

Mr. Walker further added: "Simplified manufacturing, compact supply chains, flexible production that can scale quickly, reduced foreign dependencies, lower carbon output, and more affordable prefilled solutions are what the U.S. and the world needs right now – for commercial use, public health campaigns, and emergency response. And that's exactly the kind of innovation we are focused on at Apiject."

BFS is highly flexible in container design and sizes to accommodate a wide range of medical uses – including eye drops, ear drops, nasal drops, wound care and sterile water. And now it will be used for injections and soon inhalants and infusions. In 2004, the FDA formally recognized BFS as an advanced aseptic process. In its guidance document, *Sterile Drug Products*

Produced by Aseptic Processing – Current Good Manufacturing Practice, the FDA defined BFS as an “automated process by which containers are formed, filled, and sealed in a continuous operation.”

With BFS at its core, the Apiject system reduces costs, complexity, and supply chain risks. It offers a significant improvement over the multi-step, multi-factory process of making and then filling glass drug containers. What’s more, manufacturing the Apiject device creates less than half the carbon output of a glass vial and syringe, and even uses less plastic than the traditional syringe itself.

Apiject’s underlying technology was developed, in part, through an Other Transaction Agreement and Contract for ~$181M million from the U.S. Department of Health and Human Services (HHS), Administration for Strategic Preparedness and Response (ASPR) during President Trump’s first term in office. The project highlights America’s renewed commitment to accelerate the building of new U.S.-based, high-speed, population-scale capacity for pharmaceutical manufacturing that reduces the country’s dependence on foreign suppliers, most notably China and India.

Under the agreement with HHS-ASPR, and with the contract management support of the U.S. Department of Defense, Apiject delivered an emergency domestic fill-finish capacity, on-time and on-budget, that served as a backup in the event of critical supply disruptions for traditional injection materials. Throughout the development of its technology and device platform, Apiject has been supported by an equal amount of private sector investment, making this a true public-private partnership.

As a medical technology company, Apiject works with pharmaceutical organizations to design and help manufacture scalable and affordable prefilled drug delivery systems that enable injectable medicines and vaccines to reach more patients across the world. Apiject’s simple, lightweight and sterile BFS Container and Needle Hub with Connector are easily push-assembled by a healthcare professional just prior to patient injection. Apiject recently announced a strategic collaboration with Amneal Pharmaceuticals, an integrated U.S.-based biopharmaceutical company, to expand domestic production of Apiject’s BFS-based injectable platform at Amneal's Brookhaven, New York facility.

Glycopyrrolate is indicated for use in adults as adjunctive therapy for the treatment of peptic ulcer by reducing the amount of acid produced. Apiject’s device is designed to be drug agnostic, and this NDA is the first of future combination product filings leveraging the Apiject system currently in development.

Dr. Molly Weaver, Chief Operating Officer and NDA Project Leader, said: “Almost five years of intensive R&D has prepared BFS – drug containers, devices, process equipment – to play a critical role in Apiject’s innovative platform across all major routes of injectable drug administration. Our innovation team, led by Apiject co-founder Marc Koska, the inventor of the K-1 auto-disabled syringe credited with saving millions of lives across the globe, together with our device and process teams focused on product development, quality, and regulatory compliance, have worked hand-in-hand to create this technology and its application for public health.”

Other projects in development using Apiject technology include a nasal delivery device filled with Naloxone to treat opioid overdoses resulting from continued widespread availability of fentanyl.

About Apiject Systems, Corp

Apiject Systems, Corp. is a public-benefit medical technology company that has pioneered a new category of prefilled injection devices with economic, supply chain, and sustainability advantages over traditional offerings. Our mission is to make the safety and performance benefits of prefilled injections affordable and available for most, if not all, injections around the world. The company's technology platform is anchored by a well-established manufacturing process called Blow-Fill-Seal (BFS). BFS is a widely used sterile liquid packaging technology that has been recognized by the FDA as an advanced aseptic process. For more information, visit www.apiject.com.

Cautionary Statement on Forward Looking Statements
Certain statements contained herein, regarding matters that are not historical facts, may be forward-looking statements (as defined in the U.S. Private Securities Litigation Reform Act of 1995). Such forward-looking statements include statements regarding management's intentions, plans, beliefs, expectations, financial results, or forecasts for the future, including among other things: discussions of future operations; expected or estimated operating results and financial performance; and statements regarding our positioning, including our ability to drive sustainable long-term growth, and other non-historical statements. Words such as "plans," "expects," "will," "anticipates," "estimates," and similar words, or the negatives thereof, are intended to identify estimates and forward-looking statements. Forward-looking statements included herein speak only as of the date hereof and we undertake no obligation to revise or update such statements to reflect the occurrence of events or circumstances after the date hereof.

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