



FDA Reaffirms Distinction Between Fluoropolymers and PFAS of Concern

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By: David H. Quigley, Samantha Z. Purdy, Shivani Swami (Senior International Law Advisor)

On September 1, 2026, the Food & Drug Administration (FDA) reinforced its prior conclusion that fluoropolymers used in medical devices are safe and materially different from the per- and polyfluoroalkyl substances (PFAS) that drive most regulatory, litigation and public health concerns. Specifically, FDA added a new FAQ section to its PFAS in Medical Devices webpage, which reemphasizes that fluoropolymers possess chemical and toxicological characteristics that are distinct from other PFAS, and that the agency has evaluated fluoropolymers and found no evidence that fluoropolymer use in medical devices is harmful to public health. FDA concludes that there is no reason to restrict their continued use. Fluoropolymers remain critical components of numerous medical devices, including catheters, cardiovascular implants, tubing, wound dressings, vascular grafts, guidewires, stents and pacemaker components, due to essential properties including biocompatibility, durability, electrical resistance, lubricity and long-term stability.

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