



FDA Grants 12 Year Exclusivity to Flublok® Influenza Vaccine

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Meriden, CT — Protein Sciences Corporation announced that in a rare move, the FDA is granting exclusivity to Flublok for a period of 12 years. Flublok is the first vaccine awarded this very important status, demonstrating Flublok as a unique and game changing influenza vaccine.

The U.S. FDA determination of regulatory exclusivity means that no product similar to Flublok can be approved by the U.S. FDA before January 16, 2025.

“The FDA’s designation prevents a generic product maker from capitalizing on the hard work of our team,” said Manon Cox, President and CEO of Protein Sciences Corporation.

“We are delighted that the FDA recognizes Flublok as a singular innovation in the prevention of an important and often deadly disease caused by the influenza virus.”

“I am honored to be representing Protein Sciences Corporation for nearly 20 years on matters of legal exclusivity,” said Tom Kowalski, Esq., shareholder with Vedder Price, P.C.

“This biologics regulatory exclusivity is only the third of such exclusivities granted by the U.S. FDA under the Affordable Care Act, and the only one for an influenza vaccine.”

Flublok Safety Information

Flublok is approved for people 18 and older to prevent influenza disease. The most common side effect from Flublok is pain at the site of injection.



Headache, fatigue or muscle ache may occur.

Tell the doctor if you have ever experienced Guillain-Barré syndrome (severe muscle weakness) or have had a severe allergic reaction to any component of Flublok vaccine.

Vaccination with Flublok may not protect all individuals. Clinical effectiveness in adults 50 and older is based on the immune response elicited by Flublok and not on demonstration of decreased influenza disease. Please see the complete Package Insert available at www.flublok.com or call 203-686-0800 for more information.

*Flublok demonstrated a higher antibody response to the A strains during 2 clinical trials in adults ≥50 years old.

The B strain antibody response was comparable to traditional trivalent vaccines.

Learn more at www.proteinsciences.com and www.flublok.com.