

Approval Date: [July 2, 2020](#)

Product: Flublok Quadrivalent

Proper Name: Influenza Vaccine

Manufacturer: Protein Sciences Corporation

Indication: For active immunization against disease caused by influenza A subtype viruses and influenza type B viruses contained in the vaccine.

Description: Flublok Quadrivalent [Quadrivalent Influenza Vaccine] is a sterile, clear, colorless solution of recombinant hemagglutinin (HA) proteins from four influenza viruses for intramuscular injection. It contains purified HA proteins produced in a continuous insect cell line (expresSF+®) that is derived from Sf9 cells of the fall armyworm, *Spodoptera frugiperda* (which is related to moths, caterpillars and butterflies), and grown in serum-free medium composed of chemically-defined lipids, vitamins, amino acids, and mineral salts.

BLA: 125285

Regulatory Milestone:

Flublok (trivalent formulation) was licensed in the United States on 16 January 2013 (STN 125285/0) for persons 18-49 years of age. Accelerated approval was granted on 29 October 2014 (STN 125285/78) to extend the use of Flublok to persons 50 years of age and older and was based on safety and non-inferior immunogenicity results from three clinical studies. At CBER's request, PSC agreed to conduct a clinical endpoint study in persons 50 years and older to support traditional approval due to more limited data relating hemagglutination inhibition (HI) antibody titers from

non-egg-based vaccines with protective immunity. To fulfill the accelerated approval requirement to confirm clinical benefit, it was agreed that PSC could use a quadrivalent formulation of Flublok (Flublok Quadrivalent) in the study in persons 50 years of age and older (PSC12). PSC12 was a Phase 3, relative vaccine efficacy, immunogenicity and safety clinical trial. PSC also conducted a Phase 3, non-inferior immunogenicity and safety study (PSC16) to support the licensure of Flublok Quadrivalent in persons 18-49 years of age.

PDUFA Goal Date: October 7, 2016

Package Insert: [Package Insert - Flublok Quadrivalent](#)

Summary Basis for Regulatory Approval: [October 7, 2016 Summary Basis for Regulatory Action - Flublok Quadrivalent](#)

European Public Assessment Report: None

Advisory Committee:

A VRBPAC meeting was held on [November 19, 2009](#), for the original Flublok licensing application (STN 125285/0) and there were no issues associated with this supplement that required a new Advisory Committee meeting.

NCT Numbers:

- NCT02285998
- NCT03617523
- NCT01959945
- NCT04460781
- NCT03694392
- NCT04523324
- NCT03460743
- NCT03969641
- NCT03945825
- NCT03598439
- NCT03658629
- NCT03734237
- NCT03722589
- NCT03965195
- NCT02600585
- NCT04576377

EudraCT Numbers: None

Publications:

- Dunkle, L. M., Izikson, R., Patriarca, P. A., Goldenthal, K. L., Muse, D., & Cox, M. (2017). Randomized Comparison of Immunogenicity and Safety of Quadrivalent Recombinant Versus Inactivated Influenza Vaccine in Healthy Adults 18-49 Years of Age. *The Journal of infectious diseases*, 216(10), 1219–1226. <https://doi.org/10.1093/infdis/jix478>
- Grohskopf, L. A., Sokolow, L. Z., Broder, K. R., Walter, E. B., Bresee, J. S., Fry, A. M., & Jernigan, D. B. (2017). Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices - United States, 2017-18 Influenza Season. *MMWR. Recommendations and reports : Morbidity and mortality weekly report. Recommendations and reports*, 66(2), 1–20. <https://doi.org/10.15585/mmwr.rr6602a1>
- Dunkle, L. M., & Izikson, R. (2016). Recombinant hemagglutinin influenza vaccine provides broader spectrum protection. *Expert review of vaccines*, 15(8), 957–966. <https://doi.org/10.1080/14760584.2016.1203261>
- Barr, I. G., Donis, R. O., Katz, J. M., McCauley, J. W., Odagiri, T., Trusheim, H., Tsai, T. F., & Wentworth, D. E. (2018). Cell culture-derived influenza vaccines in the severe 2017-2018 epidemic season: a step towards improved influenza vaccine effectiveness. *NPJ vaccines*, 3, 44. <https://doi.org/10.1038/s41541-018-0079-z>