

Approval Date: [July 7, 2017](#)

Product: Flublok

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 [Influenza Vaccine] is a sterile, clear, colorless solution of recombinant hemagglutinin (HA) proteins from three influenza viruses for intramuscular injection.

BLA: 125285

Regulatory Milestone:

Flublok was licensed in the United States for persons 18-49 years of age on January 16, 2013. and PSC06) in persons 50 years and older were included in the original license application. Members of a Vaccines and Related Biological Products Advisory Committee (VRBPAC) that met on November 19, 2009, to discuss the safety and efficacy of Flublok in persons 18 years and older, expressed concerns regarding the relatively small size of the Flublok safety database in all age groups, particularly in persons 50 years of age and older. PSC submitted STN 125285/78 on October 31, 2013. CBER issued a Refuse to File (RTF) letter on December 13, 2013, because the supplement was incomplete and inadequately organized. PSC requested a meeting which was scheduled for January 22, 2014, during which CBER advised PSC on how to correct the deficiencies. PSC provided a revised supplement (Amendment 8) on February 18, 2014 and

requested that it be filed over protest (FOP). CBER issued a FOP acknowledgment letter to PSC on March 6, 2014 stating that the supplement had been filed on February 18, 2014, with a new action date of October 29, 2014.

PDUFA Goal Date: October 29, 2014

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

Summary Basis for Regulatory Approval: [October 28, 2014 Summary Basis for Regulatory Action - Flublok](#)

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:

- NCT03694392
- NCT02285998
- NCT00328107
- NCT04077424
- NCT01825200
- NCT03617523
- NCT03068949
- NCT03658629
- NCT00539864
- NCT00395174
- NCT03598439
- NCT03734237
- NCT02600585
- NCT04460781
- NCT03460743
- NCT03330132
- NCT01959945
- NCT03945825
- NCT03969641
- NCT04484532
- NCT00539981
- NCT04523324
- NCT03722589
- NCT02747407
- NCT00336453
- NCT04576377
- NCT02544880
- NCT02290509
- NCT03965195
- NCT02872311

EudraCT Numbers: None

Publications:

- Cox, M. M., Patriarca, P. A., & Treanor, J. (2008). FluBlok, a recombinant hemagglutinin influenza vaccine. *Influenza and other respiratory viruses*, 2(6), 211–219.
<https://doi.org/10.1111/j.1750-2659.2008.00053.x>
- Goldenberg M. M. (2013). Pharmaceutical approval update. *P & T : a peer-reviewed journal for formulary management*, 38(3), 150–152.
- Cox, M. M., Izikson, R., Post, P., & Dunkle, L. (2015). Safety, efficacy, and immunogenicity of Flublok in the prevention of seasonal influenza in adults. *Therapeutic advances in vaccines*, 3(4), 97–108. <https://doi.org/10.1177/2051013615595595>
- Borriello, F., Pietrasanta, C., Lai, J., Walsh, L. M., Sharma, P., O'Driscoll, D. N., Ramirez, J., Brightman, S., Pagni, L., Mosca, F., Burkhart, D. J., Dowling, D. J., & Levy, O. (2017). Identification and Characterization of Stimulator of Interferon Genes As a Robust Adjuvant Target for Early Life Immunization. *Frontiers in immunology*, 8, 1772.
<https://doi.org/10.3389/fimmu.2017.01772>
- Henry, C., Palm, A. E., Utset, H. A., Huang, M., Ho, I. Y., Zheng, N. Y., Fitzgerald, T., Neu, K. E., Chen, Y. Q., Krammer, F., Treanor, J. J., Sant, A. J., Topham, D. J., & Wilson, P. C. (2019). Monoclonal Antibody Responses after Recombinant Hemagglutinin Vaccine versus Subunit Inactivated Influenza Virus Vaccine: a Comparative Study. *Journal of virology*, 93(21), e01150-19. <https://doi.org/10.1128/JVI.01150-19>
- Henry, C., Palm, A. E., Utset, H. A., Huang, M., Ho, I. Y., Zheng, N. Y., Fitzgerald, T., Neu, K. E., Chen, Y. Q., Krammer, F., Treanor, J. J., Sant, A. J., Topham, D. J., & Wilson, P. C. (2019). Monoclonal Antibody Responses after Recombinant Hemagglutinin Vaccine versus Subunit Inactivated Influenza Virus Vaccine: a Comparative Study. *Journal of virology*, 93(21), e01150-19. <https://doi.org/10.1128/JVI.01150-19>