Approval Date: July 2, 2020

Product: Fluzone Quadrivalent, Fluzone High-Dose Quadrivalent, Fluzone, Intradermal Quadrivalent, Fluzone Quadrivalent Southern Hemisphere

Proper Name: Influenza Vaccine

Manufacturer: Sanofi Pasteur Inc.

Indication:

- **Fluzone High-Dose Quadrivalent:** For active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B viruses contained in the vaccine.
- **Fluzone Quadrivalent:** For active immunization for the prevention of influenza disease caused by influenza virus subtypes A and type B viruses contained in the vaccine.
- **Fluzone Intradermal Quadrivalent:** For active immunization of persons 18 through 64 years of age for the prevention of influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.
- **Fluzone Quadrivalent Southern Hemisphere:** For active immunization against influenza disease caused by influenza virus subtypes A and types B present in the vaccine.

Description: Fluzone Quadrivalent (Influenza Vaccine) for intramuscular injection is an inactivated influenza vaccine, prepared from influenza viruses propagated in embryonated chicken eggs

BLA: BL 103914

Regulatory Milestone:

The Fluzone-QIV formulation was first approved on June 7, 2013, under STN 103914/5574 for use in persons 6 months of age and older.

PDUFA Goal Date: January 28, 2019

Package Insert:

- Package Insert - Fluzone High-Dose Quadrivalent
- Package Insert - Fluzone Quadrivalent
- Package Insert - Fluzone Intradermal Quadrivalent
- Package Insert - Fluzone Quadrivalent Southern Hemisphere

Summary Basis for Regulatory Approval: January 18, 2019 Summary Basis of Regulatory Action

European Public Assessment Report: No data

Advisory Committee:

This BLA was not discussed at a VRBPAC meeting because review of this submission did not identify concerns or issues for which the Agency would have benefited from an advisory committee discussion

NCT Numbers:

- NCT02539108
- NCT01946425
- NCT02222870
- NCT02908269
- NCT04109222
- NCT04551677
- NCT03617523
- NCT03308825
- NCT02258334
- NCT02563093
- NCT01946438
- NCT04304768

- NCT03088904
- NCT03888989
- NCT02600585
- NCT04576702
- NCT04487041
- NCT03328325
- NCT02553343
- NCT02207413
- NCT02500680
- NCT03694392
- NCT01712984
- NCT03743688
- NCT02915302
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- NCT04451954
- NCT02876159
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- NCT02307851
- NCT02290509
- NCT02860039
- NCT02148211
- NCT03158038
- NCT03736759
- NCT03734237

EudraCT Numbers:

- 2014-002599-95
- 2015-002973-39
- 2012-000218-12

- 2016-004753-33
- 2019-004721-24
- 2015-000175-27

Publications:

- Gorse, G. J., Falsey, A. R., Ozol-Godfrey, A., Landolfi, V., & Tsang, P. H. (2015). Safety and immunogenicity of a quadrivalent intradermal influenza vaccine in adults. Vaccine, 33(9), 1151–1159. https://doi.org/10.1016/j.vaccine.2015.01.025
- Jain, V. K., Domachowske, J. B., Wang, L., Ofori-Anyinam, O., Rodríguez-Weber, M. A., Leonardi, M. L., Klein, N. P., Schlichter, G., Jeanfreau, R., Haney, B. L., Chu, L., Harris, J. S., Sarpong, K. O., Micucio, A. C., Soni, J., Chandrasekaran, V., Li, P., & Innis, B. L. (2017). Time to Change Dosing of Inactivated Quadrivalent Influenza Vaccine in Young Children: Evidence From a Phase III, Randomized, Controlled Trial. Journal of the Pediatric Infectious Diseases Society, 6(1), 9–19. https://doi.org/10.1093/jpids/piw068
- Statler, V. A., Albano, F. R., Airey, J., Sawlwin, D. C., Graves Jones, A., Matassa, V., Heijnen, E., Edelman, J., & Marshall, G. S. (2019). Immunogenicity and safety of a quadrivalent inactivated influenza vaccine in children 6-59 months of age: A phase 3, randomized, noninferiority study. Vaccine, 37(2), 343–351. https://doi.org/10.1016/j.vaccine.2018.07.036
- Agarkhedkar, S., Chhatwal, J., Kompithra, R. Z., Lalwani, S. K., Narayan, A., Muninarayanaswam, V., Gogtay, N., Dotter, K., & Gresset-Bourgeois, V. (2019). Immunogenicity and safety of an intramuscular split-virion quadrivalent inactivated influenza vaccine in individuals aged ≥ 6 months in India. Human vaccines & immunotherapeutics, 15(4), 973–977. https://doi.org/10.1080/21645515.2019.1565259
- Chang, L. J., Meng, Y., Janosczyk, H., Landolfi, V., Talbot, H. K., & QHD00013 Study Group (2019). Safety and immunogenicity of high-dose quadrivalent influenza vaccine in adults ≥65 years of age: A phase 3 randomized clinical trial. Vaccine, 37(39), 5825–5834. https://doi.org/10.1016/j.vaccine.2019.08.016