

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

**Product:** Flulaval Quadrivalent

**Proper Name:** Influenza Vaccine

**Manufacturer:** ID Biomedical Corporation of Quebec

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

**Description:** FLULAVAL QUADRIVALENT, Influenza Vaccine, for intramuscular injection, is a quadrivalent, split-virion, inactivated influenza virus vaccine prepared from virus propagated in the allantoic cavity of embryonated hens' eggs.

**BLA:** BL 125163

**Regulatory Milestone:**

FluLaval was licensed in the U.S. on October 5, 2006, for the prevention of influenza subtypes A and type B contained in the vaccine under the accelerated approval regulations. A clarification letter was issued to GSK on June 1, 2011, containing PREA-related PMRs. Agreement was reached between CBER and GSK at a Type C meeting held on March 18, 2014, about the sample size and safety and immunogenicity endpoints for the primary supportive study, FLU Q-QIV-022.

**PDUFA Goal Date:** November 26, 2016

**Package Insert:** [Package Insert - FluLaval Quadrivalent](#)

**Summary Basis for Regulatory Approval:** [November 18, 2016 Summary Basis for Regulatory Action - FluLaval Quadrivalent](#)

**European Public Assessment Report:** [Human medicine European public assessment report \(EPAR\): Supemtek](#)

**Advisory Committee:**

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

**NCT Numbers:**

- NCT02148211
- NCT03598439
- NCT01974895
- NCT03694392
- NCT02242643
- NCT02831751
- NCT02768805
- NCT02222870
- NCT02539108
- NCT01946425
- NCT02908269
- NCT03438487
- NCT04109222
- NCT03965195
- NCT01959945
- NCT02474901
- NCT04551677
- NCT04460781
- NCT02563184
- NCT03888989
- NCT03328325
- NCT03617523
- NCT03686514
- NCT03701061
- NCT03308825
- NCT04439695
- NCT03553940
- NCT01991587
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- NCT03722589
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- NCT03739112
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- NCT03658629
- NCT01992094
- NCT03312699
- NCT03615482
- NCT03318315
- NCT03068949
- NCT01954251
- NCT02860039
- NCT03734237

**EudraCT Numbers:** None

**Publications:**

- 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>