

**Approval Date:** [February 6, 2020](#)

**Product:** FluLaval

**Proper Name:** Influenza Virus Vaccine

**Manufacturer:** ID Biomedical Corporation of Quebec

**Indication:** Active immunization for the prevention of disease caused by influenza A subtype viruses and type B virus contained in the vaccine. FLULAVAL is approved for use in persons 6 months of age and older.

**Description:** FLULAVAL, Influenza Vaccine, for intramuscular injection, is a trivalent, 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 PMR. 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](#)

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

European Public Assessment Report: No data available

**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:**

- NCT03701061
- NCT00812110
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- NCT00835926
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- NCT02446912
- NCT01173601

**EudraCT Numbers:**

- 2008-001445-26

**Publications:**

- Roy-Ghanta, S., Van der Most, R., Li, P., & Vaughn, D. W. (2014). Responses to A(H1N1) pdm09 influenza vaccines in participants previously vaccinated with seasonal influenza vaccine: a randomized, observer-blind, controlled study. *The Journal of infectious diseases*, 210(9), 1419–1430. <https://doi.org/10.1093/infdis/jiu284>
- Baras, B., Bouveret, N., Devaster, J. M., Fries, L., Gillard, P., Sanger, R., & Hanon, E. (2008). A vaccine manufacturer's approach to address medical needs related to seasonal and pandemic influenza viruses. *Influenza and other respiratory viruses*, 2(6), 251–260. <https://doi.org/10.1111/j.1750-2659.2008.00054.x>
- Additional flu vaccine. (2006). *FDA consumer*, 40(6), 4.