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FDA grants approval to GSKâ??s FLUARIXÂ® QUADRIVALENT

15 January 2018 | News

GSK receives FDA approval for expanded indication for FLUARIXÂ® QUADRIVALENT (Influenza Vaccine) for persons 6 months and older



GlaxoSmithKline (GSK) is leading research-based pharmaceutical and healthcare company.

GSK announced about the receiving approval from the US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research expanding the indication for FLUARIX® QUADRIVALENT (Influenza Vaccine) to include use in persons 6 months and older.

Seasonal influenza (the "flu") is a contagious respiratory illness, caused by flu viruses. There are two main types of flu viruses, A and B, that spread between people and can cause mild to severe illness.

According to the US Centers for Disease Control and Prevention (CDC), the best tool available to help protect yourself and those around you against the flu is to get vaccinated.

Prior to the FDA approval, the vaccine was only approved for active immunization against influenza A subtype viruses and type B viruses, in persons 3 years of age and older.

With this approval, providers will be able to use the same dose of FLUARIX® QUADRIVALENT (15 ug of hemagglutinin per virus strain in 0.5 mL) to cover all eligible persons from 6 months of age and up.

The supplemental Biologics License Application was based on a Phase III pivotal study of the efficacy of FLUARIX® QUADRIVALENT in children 6 months through 35 months of age and on two supportive studies.