FDA Expands Use of Quadrivalent Flu Vaccine *(FluLaval)* to Infants

Megan Brooks | November 21, 2016

The US Food and Drug Administration (FDA) has expanded the indication for GlaxoSmithKline's quadrivalent influenza vaccine (*FluLaval*) to include children aged 6 months and older, the company has announced.

FluLaval quadrivalent influenza vaccine was first approved in 2013 in the United States for the prevention of influenza A subtype viruses and type B viruses in people 3 years of age and older.

Before approval of an expanded age indication for FluLaval quadrivalent, providers who preferred prefilled syringes had to order and stock two separate influenza vaccines in order to be able to immunize all patients, the company notes in a news release.

"With this approval, providers are now able to use the same dose of FluLaval quadrivalent (15 µg of hemagglutinin per virus strain in 0.5 mL) to vaccinate all recommended persons aged 6 months and older."

Approval of the supplemental biologics license application for FluLaval in children as young as 6 months of age was based on one phase 3 pivotal study and three supportive clinical studies conducted in children aged 6 months through 35 months, the company said.

The Centers for Disease Control and Prevention recommends that everyone aged 6 months and older get a seasonal influenza vaccine.

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