

## **New Flu Shot Approved By FDA**

On January 16, 2013 the U.S. Food and Drug Administration approved Flublok® for the prevention of seasonal influenza in people 18 through 49 years of age. Flublok® is an insect virus-based (baculovirus) flu vaccine that does not require eggs or influenza virus for production. It is the first trivalent influenza vaccine made using the baculovirus expression system and recombinant DNA technology. This new production process allows for production of large quantities of hemagglutinin, the active ingredient in all inactivated influenza vaccines essential for entry of the virus into cells. This process also allows for those with an egg allergy to receive a yearly influenza vaccine.

Flublok® contains three, full-length, recombinant hemagglutinin proteins to help protect against two influenza virus A strains, H1N1 and H3N2, and one influenza virus B strain. A multi-center, randomized, placebo-controlled trial with 2,344 patients in the treatment arm showed Flublok® to be 44.6% effective against all circulating influenza strains, not just the strains matching those included in the vaccine. The most commonly reported adverse events were pain at injection site, headache, fatigue or lack of energy, and muscle aches. These are consistent with adverse events associated with egg-based, inactivated influenza vaccines. Flublok® has a shelf life of 16 weeks from the date of manufacture. Protein Sciences Corporation, the manufacturer, reports that Flublok® will be available in limited supply for the current influenza season and will be widely available for the 2013-2014 influenza season.

### References:

- U.S. Food and Drug Administration. (2013). FDA approves new seasonal influenza vaccine made using novel technology [Press release]. Retrieved from <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm335891.htm>.
- Treanor JJ, El Sahly H, King J, Graham I, Izikson R, Kohberger R, Patriarca P, Cox M. Protective efficacy of a trivalent recombinant hemagglutinin protein vaccine (FluBlok®) against influenza in healthy adults: a randomized, placebo-controlled trial. Vaccine. 2011 Oct 13;29(44).

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