

FDA approves new type of flu vaccine

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Flublok easier to produce quickly and in large quantities, agency says.

(HealthDay)—The U.S. Food and Drug Administration has approved a novel type of flu vaccine, the agency announced Wednesday.

Flublok, as the vaccine is called, does not use the traditional method of the influenza virus or eggs in its production. Instead, it is made using an "insect virus (baculovirus) expression system and recombinant DNA technology," the FDA said in a news release. This will allow vaccine maker Protein Sciences Corp., of Meriden, Conn., to produce Flublok in large quantities, the agency added.

The vaccine is approved for use in those aged 18 to 49.

"This approval represents a technological advance in the manufacturing of an <u>influenza vaccine</u>," said Dr. Karen Midthun, director of the FDA's



Center for Biologics Evaluation and Research. "The new technology offers the potential for faster start-up of the vaccine manufacturing process in the event of a pandemic, because it is not dependent on an egg supply or on availability of the <u>influenza virus</u>."

While the technology is new to <u>flu vaccine</u> production, it has been employed in the making of vaccines that prevent other infectious diseases, the agency noted.

As it does with all influenza vaccines, the FDA will assess Flublok before each <u>flu season</u>. In research conducted at various sites in the United States, Flublok was about 45 percent effective against all circulating <u>influenza strains</u>, not just the strains that matched those in the vaccine. The most commonly reported adverse reactions included pain at the site of injection, headache, fatigue and muscle aches—events also typical for conventional flu vaccines, the agency said.

The new flu vaccine could not have come at a better time, with the flu season well under way and sporadic shortages of both the traditional flu vaccine and the <u>flu treatment</u> Tamiflu.

"We have received reports that some consumers have found spot shortages of the vaccine," FDA Commissioner Dr. Margaret Hamburg said Monday on her blog on the agency's website.

So far, more than 128 million doses of flu vaccine have been distributed, Hamburg said, but not all the doses have been administered to people yet.

She said that people who already have the flu may also be experiencing local shortages of Tamiflu.

"We do anticipate intermittent, temporary shortages of the oral



suspension form of Tamiflu—the liquid version often prescribed for children—for the remainder of the flu season. However, FDA is working with the manufacturer to increase supply," she said.

Flu season typically peaks in January or February but can extend as late as May. This flu season is turning out to be more severe than last year's.

Officials at the U.S. Centers for Disease Control and Prevention said on Friday that 47 states were reporting widespread influenza activity, although flu case numbers were beginning to subside in some regions, especially in the Southeast, where the flu showed up first.

It's still not too late to get a flu shot to help protect yourself, Hamburg stressed. She noted that it takes about two weeks after vaccination for your body to develop an immune response to provide protection against the flu.

People who want to get vaccinated can visit flu.gov, click on the "Flu Vaccine Finder," enter their zip code and find a list of clinics, supermarkets, pharmacies and other flu vaccination locations in their neighborhoods.

But before you go to one of the locations, call ahead to confirm that they have the flu vaccine, Hamburg advised.

According to recommendations from the CDC, all adults and children who are at least 6 months old should receive a flu vaccination each year. The best time to get vaccinated is in the fall.

More information: The U.S. Centers for Disease Control and Prevention has more about the <u>flu and flu vaccine</u>.



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