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FDA approves H5N1 avian influenza vaccine

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(HealthDay)—The U.S. Food and Drug Administration has approved the first adjuvanted vaccine for the prevention of H5N1 influenza in adults at greater-than-average risk of exposure.

While most strains of avian influenza don't infect people, the H5N1 virus has caused "serious illness and death in people outside of the United States, mostly among people who have been in close contact with infected and ill poultry," the agency said in a news release announcing the approval.

The shot, called the Influenza A (H5N1) Virus Monovalent Vaccine, has been developed "in the event that the H5N1 avian influenza virus develops the capability to spread efficiently from human to human, resulting in the rapid spread of the disease across the globe," the FDA added.

The vaccine, produced by a Canadian subsidiary of GlaxoSmithKline, is not intended for commercial distribution, the FDA said. It's designed to

be administered in two doses given three weeks apart.

In clinical testing involving some 3,400 adults, the most common side effects included injection-site pain and swelling, muscle aches, headache, and fatigue.

More information: More Information