

FDA approves new swine flu vaccine

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Health and Human Services Secretary Kathleen Sebelius testifies on Capitol Hill in Washington, Tuesday, Sept. 15, 2009, before the House Energy and Commerce Committee hearing on Pandemic Flu Preparedness. At left is Dr. Anne Schuchat of the Centers for Disease Control and Prevention. (AP Photo/Susan Walsh)

(AP) -- The Food and Drug Administration approved the new swine flu vaccine Tuesday, a long-anticipated step as the government works to get vaccinations under way next month. Health and Human Services Secretary Kathleen Sebelius announced the vaccine's approval to Congress - and said she hopes to get the first limited supplies distributed early in October.

The bulk of [vaccine](#) will start arriving Oct. 15, and Sebelius said it

should be available at 90,000 sites around the country.

"We will have enough vaccine available for everyone" eventually, Sebelius said - everyone who wants it, that is.

The government has ordered 195 million doses for now but may order more if needed, she said. Typically 100 million Americans seek flu vaccine every year.

But the vaccine, which protects against what doctors prefer to call the 2009 H1N1 flu strain, won't arrive all at once. About 45 million doses are expected by mid-October. That's why the government wants the people most likely to catch swine flu, and to suffer complications from it, to be first in line - including children and pregnant women.

FDA licensure means that the government has certified the vaccine is made properly and meets specific manufacturing and quality standards. Separately, the National Institutes of Health is studying the vaccine dosage and safety. Last week, the NIH announced that one dose appears to protect adults - and that that protection kicks in eight to 10 days after the shot.

Studies in children and [pregnant women](#) are continuing.

The vaccine approved Tuesday is made by CSL Ltd. of Australia; Switzerland's [Novartis](#); Sanofi-Pasteur of France; and Maryland-based Medimmune, which makes the only nasal-spray [flu vaccine](#).

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