

FDA Approval of 2009 Novel H1N1 Vaccine: Summary

FDA approved four vaccines as a strain change to each manufacturer's seasonal influenza vaccine on September 15, 2009. The presentations, age, and dosage specifications listed in the chart below. For more information, as well as the package inserts, visit FDA's website at <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

Manufacturer	Presentations	Age	Dosage ¹	Type	Package Insert
CSL Limited	-0.5 mL prefilled single-dose syringe (thimerosal free) -5 mL multi-dose vial containing 10 doses (with thimerosal)	Adults 18 years of age and older	-Single 0.5 mL dose	Inactivated virus; intramuscular injection	Link
GlaxoSmithKline ²	<i>Awaiting FDA licensure</i>				
Novartis Vaccines and Diagnostics Limited	-0.5 mL prefilled single-dose syringe (trace thimerosal) -5 mL multi-dose vial (with thimerosal)	Persons 4 years of age and older	-Two 0.5 mL doses approx. 1 month apart for children 4 to 9 -Single 0.5 mL dose for children 10-17 -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
Sanofi Pasteur Inc.	-0.25 mL prefilled single-dose syringe (thimerosal free) distinguished by pink syringe plunger rod -0.5 mL prefilled single-dose syringe (thimerosal free) -0.5 mL single-dose vial (thimerosal free) -5 mL multi-dose vial (with thimerosal)	Persons 6 months and older	-Two 0.25 mL doses approx. 1 month apart for children 6-35 months of age -Two 0.5 mL doses approx. 1 month apart for children 36 months-9 years -Single 0.5 mL dose for children 10 years and older -Single 0.5 mL dose for adults 18 and older	Inactivated virus; intramuscular injection	Link
MedImmune, LLC	-0.2 mL prefilled single-dose intranasal sprayer	Persons aged 2 to 49 years	-Two 0.2 mL doses approx. 1 month apart for children 2 to 9 -Single 0.2 mL dose for persons 10-49	LAIV; Intranasal spray	Link

1 Based on currently available information, which suggests children 6 months to 9 years of age have little or no evidence of protective antibodies to the novel H1N1 virus. It is expected that children 9 years of age and younger should be administered two doses of the vaccine, and that children and adults 10 years of age and older will need one dose. Clinical studies are underway and will provide additional information about the optimal dosage for children.

2 The GlaxoSmithKline H1N1 vaccine has not yet been approved. Based on their licensure for 2009-2010 seasonal influenza vaccine, their H1N1 vaccine can be expected to be an inactivated virus vaccine for adults 18 and older with presentations of 0.5 mL prefilled single-dose syringes (thimerosal free).