



Public Health
Division

County of Santa Cruz

HEALTH SERVICES AGENCY

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Press Release

For Immediate Release:	Media Call for available Public Information Officer
Date: December 15, 2009	Phone: 831-454-4000
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Pandemic Influenza (H1N1) 2009 Vaccine Recall:

Recalled Doses are Still Safe; No Need to be Re-vaccinated

The Centers for Disease Control and Prevention (CDC) issued a Health Alert today announcing a voluntary recall of four lots of H1N1 Pediatric Vaccine in Pre-Filled Syringes for children age 6 months to 3 years old from one manufacturer. This type of injectable vaccine does not constitute a large percentage of H1N1 vaccine supply. Santa Cruz County Public Health emphasizes that this recall is not related to vaccine safety.

Routine, ongoing testing of vaccine is done before and after it has been shipped to providers. One manufacturer, Sanofi Pasteur, notified the CDC and Food and Drug Administration (FDA) that the potency in four lots of pediatric syringes was found to have dropped after the vaccine was distributed. The vaccine in these four lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen.

There is no need to re-vaccinate those who received vaccine from these lots. If a child age 6-35 months received a first dose from one of these lots, only a second dose will be required, as would be the case for all children this age. If a child age 6-35 months received a second dose from one of these lots, there is no need to give a third dose. CDC's recommendation is for all children less than 10 years old to get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response.

Santa Cruz County Health Officer Dr. Poki Namkung said: "Parents who have already vaccinated their children should feel confident they are protecting their children's health. It remains true that for children age 6 months through 9 years, a second dose is required to reach full immunity. All children in that age group need their second dose to be fully protected."

This voluntary recall does not change H1N1 vaccination recommendations. Of the vaccine affected by this recall, California received 47,800 doses, of which Santa Cruz County Public Health has determined we administered 73 doses in our walk-in clinics on 12/09 and 12/12. We have directly alerted all healthcare providers who may have received this vaccine. The manufacturer will be contacting all who received this specific vaccine with directions for returning any unused vaccine from these lots. Sanofi Pasteur is investigating what caused the problem. The same vaccine packaged in other dosing forms, such as pre-filled syringes for older children, adults, and multi-dose vials, continues to meet required specifications. This recall does not affect H1N1 vaccine produced by other manufacturers.

Our website at www.santacruzhealth.org/SwineFlu and information line at 454-4343 will be updated and additional press notification will be provided as needed.



Public Health
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