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## News Release

### **Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur 2009**

### **H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes**

**El Paso County, CO**—The El Paso County Department of Health and Environment received 200 H1N1 vaccine doses on Dec. 7 that are now being recalled. The Department was notified of this recall this morning. The Manufacturer Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in the identified lot numbers of pediatric syringes that had been distributed to providers was later found to have dropped below a pre-specified limit, meaning the potency is below standard, but this is not a safety concern. Providers of H1N1 vaccine in the community, who received their supplies from the Health Department, will be notified and asked not to use anymore of that lot number and will be asked if they would like to order more vaccine. The Health Department's five large-scale community clinics (Coronado, Harrison High Schools, New Life Church, The Hangar; and The Citadel held on Dec. 5) did not use any pre-filled syringes to give vaccinations. The Health Department is sending a notification to providers in the community who received their H1N1 vaccine supplies from McKesson, asking them to check remaining pre-filled vaccine lot numbers and to not administer it to children.

#### **Important points related to this voluntary H1N1 non-safety related vaccine recall:**

- **There are no safety concerns with these recalled lots of 2009 H1N1 vaccine.** All lots successfully passed pre-release testing for purity, potency and safety.
- Only specified lots of the 2009 H1N1 pediatric vaccine for children 6-35 months in pre-filled syringes are affected.
- **There is no need to re-administer a dose to those who received vaccine from these lots.** The vaccine potency is only slightly below the "specified" range. The vaccine in these

lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen.

- All children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. Therefore, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.
- When feasible, the same type of vaccine (live attenuated or inactivated) should be used in a two-dose schedule. Mixed schedules however, are preferable to not completing the series.
- Children should receive both doses of 2009 H1N1 vaccine from the same type of vaccine (i.e., both doses as inactivated, injectable; or both doses as live, attenuated, nasal spray vaccine).
- All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution centers. The vaccine provided in multi-dose vials and the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

For more information about H1N1 flu and where to find vaccine, visit [www.elpasocountyhealth.org](http://www.elpasocountyhealth.org), or call 2-1-1, the Pikes Peak United Way's Health and Human services phone line, or the toll-free Colorado Help Line at (877) 462-2911.

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