

December 29, 2009

To: Kern County Health Care Providers

RE: Non-Safety Voluntary Recall of H1N1 Nasal Spray Vaccine

According to the CDPH Immunization Branch there have been a total of 8,610 doses of the recalled lot numbers for monovalent 2009 (H1N1) nasal spray vaccine manufactured by MedImmune that were shipped to a total of 30 providers in Kern County. The Public Health department has received 3,400 doses of the affected lot numbers and recall efforts are under way.

If the vaccine has already been administered to your patients, there is no need to re-administer. If it was the first dose, as is recommended for children 9 years or younger, a second dose will still be required. If it was the second dose, there is still no recommendation to re-administer vaccine. If any provider currently has recalled vaccine, please set these doses aside and label them DO NOT USE until you are contacted by MedImmune.

On December 18 and 21, MedImmune notified CDC and FDA that the potency of 13 lots of monovalent 2009 (H1N1) nasal spray vaccine had decreased below a pre-specified limit or were at risk of falling below that limit in the next week. **This slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. There are no safety concerns with these lots of 2009 H1N1 vaccine.** All lots successfully passed pre-release testing for purity, potency and safety. However, because their potency is now or might soon be below the specified lower limit, **MedImmune will contact providers directly and send directions for returning any unused vaccine from these lots.**

The 13 lots subject to the recall were shipped to CDC's contract distributor in October and early November. **Most of the doses are believed to have already been administered while fully potent and within specifications.** However, there are almost certainly some doses that have not yet been used.

The affected lot numbers are:

- 500754P
- 500751P
- 500756P
- 500757P
- 500758P
- 500759P
- 500760P
- 500761P
- 500762P
- 500763P
- 500764P
- 500765P
- 500776P

If you have any other questions, regarding the voluntary recall of MedImmune H1N1 nasal spray vaccine, please contact the KCDPH Immunization Coordinator Ann Walker at (661) 868-0562.

