

The Burlington County Health Department has been informed that some Flu Mist is being recalled by MedImmune due to a decrease in potency detected during recent quality control testing. We understand that this may raise concerns among school officials and parents regarding the effectiveness of the vaccine that has been used at school clinics throughout the county since October. However, we have been assured by MedImmune, the CDC, and the FDA that the Flu Mist used at all school clinics to date was effective at the time of use. The decrease in potency that has prompted this current recall occurred over the course of just the last week. It is this recent decrease in potency that has prompted MedImmune to recall the unused doses from the affected lots.

It is important to point out that the recall is not safety-related. As part of its quality assurance program, the manufacturer of the nasal spray monovalent 2009 H1N1 flu vaccine, MedImmune, performs routine, ongoing stability testing of the vaccine. Stability testing means measuring the strength (also called potency) of the vaccine over time to make sure it does not go below a pre-specified limit during the vaccine's "shelf life." On December 18 and 21, the manufacturer notified CDC and FDA that the potency in 13 batches (called "lots") of nasal spray vaccine had decreased below the pre-specified limit or were at risk of falling below that limit within the upcoming week. Subsequent lots of the vaccine were produced with a slightly higher potency to decrease the chance that they would fall "below specification" before their expiration dates.

There were approximately 4.7 million doses in these lots that were distributed to providers. Most of the doses were shipped to vaccine providers in October and early November, during a time when the vaccine potency was still at or above the recommended level. The Burlington County Health Department received 7340 doses from the affected batches and has used 7017 of them at our various clinics. The remaining 323 doses have now been pulled and will be returned to MedImmune as part of the recall.

Persons who received vaccine from the recalled lots do not need to take any special actions. There is no need to re-administer a dose to those who received vaccine from the recalled lots. As is recommended for all 2009 H1N1 vaccines, all children younger than 10 years old should get the recommended two doses of 2009 H1N1 vaccine approximately a month apart for the optimal immune response. Therefore, children younger than 10 years old who have only received one dose of the nasal spray vaccine thus far should still receive a second dose of 2009 H1N1 vaccine.

The Burlington County Health Department will continue to monitor the situation and adhere to all recommendations passed down from the FDA and CDC to assure the safety of all our residents.