



HEALTH DEPARTMENT

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COUNTY OF ST. CLAIR



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(810) 987-1311

NEWS RELEASE

Information Advisory Alert Update

For immediate release

DECEMBER 23, 2009

For more information contact:

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Recalled H1N1 Nasal Spray Vaccine

MedImmune, the maker of the nasal spray monovalent 2009 H1N1 flu vaccine, is recalling about 4.7 million doses of the product because the potency has slightly decreased. On December 18 and 21, MedImmune notified Centers for Disease Control and the Food and Drug Administration that the potency of 13 lots (approximately 4.7 million doses) 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 is not expected to have an impact on the protective response of the vaccine. Most of the doses are believed to have already been administered while fully potent and within specifications. There are no safety concerns with these recalled doses of 2009 H1N1 vaccine. All doses successfully passed pre-release testing for purity, potency and safety.

Furthermore, this recall does not affect 2009 H1N1 vaccine produced by other manufacturers. However, a similar recall was conducted recently which involved lots of Sanofi Pasteur's pediatric 2009 H1N1 vaccine in 0.25 mL pre-filled syringes.

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No doses of that vaccine were administered or distributed in St. Clair County.

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Locally, with this current recall, the St. Clair County Health Department



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received and administered three of the recalled lot numbers. Sixteen St. Clair County providers also received some of the affected lots. MedImmune will send providers directions for returning any unused vaccine from these lots. Again, there are no safety concerns with these recalled doses.

People who received vaccine from the recalled lots do not need to take any action. Children and adults aged 10 years and older who received the vaccine do not need any further doses of vaccine. As recommended, all children younger than 10 should get the recommended two doses of 2009 H1N1 vaccine approximately one month apart.

Free H1N1 vaccine is available at the main office of the Health Department, located at 3415 28th Street in Port Huron, from 8:15 to 11:45 on Tuesdays and Thursdays until the end of the year. Beginning in January, 2010, vaccinations will be offered at the Health Department on Tuesdays and Thursdays from 8-4:30pm.

END