

# VACCINE RECALL



MedImmune

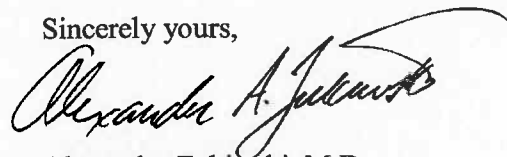
**Event 2073**  
December 22, 2009

Dear Distributor/Provider:

<b>PRODUCT</b>	<p><b>Product:</b> Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal</p> <p><b>Package:</b> Pre-filled sprayers</p> <p><b>NDC:</b> 66019-200-01 - Individual Sprayer 66019-200-05 - Tray of 5 syringes 66019-200-10 - Carton containing two trays of 5 syringes</p> <p><b>Lots:</b></p> <table border="1" data-bbox="557 758 750 1190"><tr><td>500751P</td></tr><tr><td>500754P</td></tr><tr><td>500756P</td></tr><tr><td>500757P</td></tr><tr><td>500758P</td></tr><tr><td>500759P</td></tr><tr><td>500760P</td></tr><tr><td>500761P</td></tr><tr><td>500762P</td></tr><tr><td>500763P</td></tr><tr><td>500764P</td></tr><tr><td>500765P</td></tr><tr><td>500776P</td></tr></table> <p><b>Expiration Date:</b> 19 -26 January 2010</p>	500751P	500754P	500756P	500757P	500758P	500759P	500760P	500761P	500762P	500763P	500764P	500765P	500776P
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<b>REASON</b>	<p>Routine stability testing of Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Lot 500751P revealed a slight decrease in the potency of the H1N1 component of the vaccine in early December. The vaccine met all required specifications at the time of release and has been monitored in weekly time intervals during its shelf life and has consistently met specification until the most recent test point in early December 2009. Lots 500754P, 500756P, 500757P, 500758P, 500759P, 500760P, 500761P and 500762P are expected to have the same slight decrease in potency as lot 500751. Additionally, data analysis suggests that four of the lots (500763P, 500764P, 500765P and 500776P) may expire before their labeled expiration dates and are being recalled as a precautionary measure.</p>													

<b>HEALTH EFFECTS</b>	<p>The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and MedImmune have agreed that no public health impact is expected because: 1) the decrease in potency is expected to have little if any impact on the response to vaccination and there are no safety concerns with these lots of vaccine, 2) all of the affected vaccine was shipped when the vaccine met potency requirements, and 3) most of the H1N1 influenza vaccine from these 13 lots was likely administered in October and November, during which the vaccine fully met potency requirements. In addition, 4 of the recalled lots (lots 500763P through 500776P) currently meet the specification for potency but are being recalled as a precaution because data analysis suggests the potency might decrease below specification before their labeled expiration dates.</p> <p><b>Revaccination is not necessary since the slight decrease in potency is expected to have little if any impact on the response to vaccination and most patients are likely to have been vaccinated when the product met specifications.</b></p>
<b>REQUIRED ACTION</b>	<ol style="list-style-type: none"> <li>1. <b>Stop distribution/administration of these lots immediately.</b></li> <li>2. Please carry out a physical count of your inventory and record this data on the Business Reply Card and the Packing Slip that are included with this letter.</li> <li>3. Mail the postage-paid Business Reply Card <b>even if you do not have any inventory of these lots.</b></li> <li>4. Return these lots with the Packing Slip using the prepaid UPS <i>Authorized Return Service</i><sup>SM</sup> shipping labels to: <p style="text-align: center;">Stericycle® ATTN: Event 2073 2670 Executive Drive, Suite A Indianapolis, IN 46241</p> </li> <li>5. <b>This recall is to the distributor/provider level.</b></li> </ol>
<b>OTHER INFORMATION</b>	<ul style="list-style-type: none"> <li>• <b>This Recall Involves the Influenza A (H1N1) 2009 Monovalent Vaccine Live, Intranasal Lots listed above.</b></li> <li>• <b>No other lots are being recalled.</b></li> <li>• <b>Medical questions:</b> 1-800-949-3789 (MedImmune, LLC)</li> <li>• <b>Customer Service:</b> Please contact Stericycle® at 1-866-209-9273 for shipping assistance, additional shipping labels or questions about the recall process.</li> <li>• MedImmune is conducting this recall with the full knowledge of the <b>Food and Drug Administration and the Centers for Disease Control and Prevention.</b></li> </ul>

Sincerely yours,



Alexander Zukiwski, M.D.  
Chief Medical Officer  
MedImmune, LLC