

Voluntary Recall of Influenza A (H1N1) 2009 Monovalent Vaccine
Lot Numbers UT023DA, UT028CB, UT028DA, and UT030CA

Instructions For Complying With Recall

December 16, 2009

BACKGROUND

Sanofi Pasteur is initiating a voluntary recall of 4 lots of Influenza A (H1N1) 2009 Monovalent Vaccine, pediatric dose (0.25mL) prefilled syringes.

| <u>Lot number:</u> | <u>Expiration date:</u> | <u>NDC #:</u> |
|--------------------|-------------------------|--|
| UT023DA | 4/30/2011 | 49281-650-25 (which also may be recorded as NDC # 49281-0650-25) |
| UT028CB | 4/9/2011 | 49281-650-25 (which also may be recorded as NDC # 49281-0650-25) |
| UT028DA | 4/9/2011 | 49281-650-25 (which also may be recorded as NDC # 49281-0650-25) |
| UT030CA | 3/30/2011 | 49281-650-70 (which also may be recorded as NDC # 49281-0650-70) |

Please stop using these lot numbers immediately and return all remaining inventory of these lot numbers.

No other distributed lots of Influenza A (H1N1) 2009 Monovalent Vaccine are affected.

PRODUCT ACTION

We request that you examine your inventory to determine if you have any remaining stock of the recalled lots. Please return the Business Reply Card whether or not you have remaining doses to help us determine that all existing stock has been returned.

Enclosed with this letter is a postage-paid Shipping Label and a Packing Slip with instructions on how to return the product to: Capital Returns, 6101 North 64th St, Milwaukee, WI 53218.

PATIENT ACTION

No patient action is required.

ADDITIONAL ASSISTANCE

Sanofi Pasteur will provide you with additional communication materials upon request. Please call 1-888-241-9288 for these items. For other inquiries, please contact sanofi pasteur Customer Services at 1-800-VACCINE (1-800-822-2463).

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