sanofi pasteur

The vaccines division of sanofi-aventis Group

IMPORTANT INFORMATION REGARDING FOUR LOTS OF SANOFI PASTEUR'S PEDIATRIC INFLUENZA A (H1N1) 2009 MONOVALENT VACCINE

December 16, 2009

Dear Health-care Professional:

Sanofi Pasteur, Inc. has notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that routine testing of its pediatric Influenza A (H1N1) 2009 Monovalent Vaccine in 0.25mL syringes has identified four distributed lots with lower antigen content than the specification limit.

The FDA and the CDC have determined that **there are no safety concerns** with any of these lots.

The CDC first notified grantees last Friday that one lot was impacted. We now know the following four lots are impacted:

UT023DA, UT028CB, UT028DA (NDC # 49281-650-25, which also may be recorded as NDC # 49281-0650-25), 0.25mL syringes in 10 packs.

UT030CA (NDC # 49281-650-70, which also may be recorded as NDC # 49281-0650-70), 0.25mL syringes in 25 packs.

These lots were shipped in November and are intended for children 6 through 35 months of age.

If you have unused doses from these lots, you should return them as outlined in the attached instructions.

The FDA and the CDC do not recommend repeating any doses that children received from these lots. This is because the drop in antigen content is unlikely to result in a clinically significant reduction in immune response. Children who have received one dose should receive the recommended second dose of Influenza A (H1N1) 2009 Monovalent Vaccine.

We appreciate your attention to this matter.

Sincerely,

Michael D. Decker, MD, MPH
Vice President, Scientific & Medical Affairs and Chief Medical Officer

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