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## NON-SAFETY-RELATED VOLUNTARY RECALL OF SANOFI PASTEUR 2009 H1N1 FLU VACCINE IN PRE-FILLED SYRINGES

### QUESTIONS & ANSWERS February 3, 2010

**1. Why are some of the doses of H1N1 vaccine manufactured in pre-filled syringes being recalled from the market?**

As part of its ongoing quality assurance program, Sanofi Pasteur performs routine stability testing of its 2009 H1N1 influenza vaccine after the vaccine has been shipped to health care providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can decrease over time.

Sanofi Pasteur (the manufacturer) notified the FDA that the potency of some of its pediatric and adult syringes that had been distributed between November 2009 and January 2010 were found to have dropped below a pre-specified potency after they were shipped. On February 2, 2010, Sanofi Pasteur sent health care providers instructions to return unused vaccine from the affected lots.

These actions apply only to the lots of 2009 H1N1 vaccine in pre-filled syringes manufactured by Sanofi Pasteur.

**2. What does “potency” mean for the H1N1 vaccine?**

Potency (or strength) is determined by measuring the concentration of the active ingredient (also called antigen) in the vaccine.

**3. Are there any concerns about the safety of 2009 H1N1 vaccines being recalled?**

No. There are **no safety concerns** with the recalled lots of H1N1 vaccine and **no re-administration of the vaccine is required**. All of the H1N1 vaccine lots successfully passed pre-release testing and additional post-release testing supports the conclusion that there is no cause for concern over safety.

**4. What are the lot numbers affected by this recall?**

The vaccines in pre-filled syringes affected by this recall include the following lot numbers:

UT023AA, UT023BA, UT023CA, UT023EA, UT023FA (NDC # 49281-650-25, which also may be recorded as # 49281-0650-25), 0.25 mL syringes in 10-packs

UT037AA (NDC # 49281-650-90, which also may be recorded as # 49281-0650-90), 0.5 mL syringes in 25-packs

**5. How many doses are in these lots?**

There are approximately 1.3 million doses in the lots that were distributed to health care providers. The manufacturer is recalling any doses from these lots that may still be unused.