



Oct. 19, 2009

Notice to providers regarding the Oct. 14, 2009, shipment of 2009 H1N1 vaccine from the North Dakota Department of Health warehouse

This memo applies only to 2009 H1N1 Influenza vaccine:

- Manufactured by Novartis (Fluvirin pre-filled syringes) and Sanofi Pasteur (Fluzone multi-dose vials)

And

- Shipped from the North Dakota Department of Health warehouse Oct. 14, 2009, with delivery Oct. 15, 2009

And

- In which shipment in which the temperature indicator showed temperatures out of range
 - (The freeze indicator turned red)

This memo does not apply to any shipments received directly from McKesson or to any shipment of flumist, regardless of warehouse origin.

On Oct. 14, 2009, the North Dakota Department of Health shipped orders of Fluvirin and Fluzone vaccine to North Dakota providers. On October 15, we received several calls from providers reporting that the freeze indicator showed temperatures outside of safe shipping and storage range. Preliminary investigations revealed that many of these indicators may had been incorrectly placed in the package (i.e., directly next to the ice packs).

Because we cannot know for sure why some of the temperature monitors went out of range, we are recommending that health-care providers do not use the injectable vaccine they received Oct. 15, 2009, from the North Dakota Department of Health warehouse if a temperature indicator in the vaccine shipment showed frozen temperatures (the freeze indicator turned red). In addition, those people who received this vaccine should be revaccinated as soon as vaccine is available. The vaccine poses no greater safety issue than vaccine kept within the correct temperature range. However, the ability of the vaccine to illicit an immune response may be diminished. Lost inventory will be replaced as soon as supply allows.