

News & Events

FDA NOTE TO CORRESPONDENTS

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FDA Expands Approved Use of H1N1 Vaccines to Include Infants and Children

The U.S. Food and Drug Administration has approved the use of the CSL Limited's 2009 H1N1 influenza vaccine to include children ages 6 months and older. This vaccine was previously approved only for use in adults, ages 18 years and older.

"Because children are among those most vulnerable to the 2009 H1N1 virus, having a broader range of children's vaccines available is an important step in responding to the H1N1 outbreak," said Margaret A. Hamburg, M.D., commissioner of food and drugs.

The company's 2009 H1N1 vaccine is manufactured and tested using the same well-established licensing processes that have been in place for many years for the company's seasonal flu vaccine. The expanded approval also covers the company's seasonal flu vaccine.

The approval was based on a study of the company's seasonal flu vaccine in children showing the vaccine's safety and efficacy in inducing antibodies to protect against influenza. These efficacy findings supported approval under FDA's accelerated approval regulation, which helps safe and effective medical products for serious or life-threatening diseases to become available sooner to the public.

Common adverse events experienced by children after administration of seasonal and H1N1 vaccines typically include pain, redness and swelling at the injection site as well as, in some cases, irritability, loss of appetite and drowsiness.

As with any medical product, unexpected or rare serious adverse events may occur. FDA is collaborating with the U.S. Department of Health and Human Services, including the Centers for Disease Control and Prevention, and other government agencies to enhance the capacity for adverse event safety monitoring during and after the 2009 H1N1 vaccination program.

Because CSL's seasonal and H1N1 monovalent vaccines contain a small amount of egg protein, they should not be administered to anyone allergic to eggs or egg products.

The vaccines will be available in single-dose, preservative-free, pre-filled syringes and in

multi-dose vials that contain thimerosal, a mercury derivative, as a preservative.

Both vaccines are manufactured by CSL Ltd. of Australia.

For more information, see

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>

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