FDA Approves Vaccine for 2009-2010 Seasonal Influenza

FDA NEWS RELEASE

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Media Inquiries: Peper Long, 301-796-4671, mary.long@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

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The U.S. Food and Drug Administration today announced that it has approved a vaccine for 2009-2010 seasonal influenza in the United States.

The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus that resulted in the declaration of a pandemic by the World Health Organization (WHO) on June 11, 2009. The FDA continues to work with manufacturers, international partners and other government agencies to facilitate the availability of a safe and effective vaccine against the 2009 H1N1 influenza virus.

Although this year’s seasonal vaccine is directed against other strains of influenza expected to be circulating and will not provide protection against the 2009 H1N1 influenza virus, it is still important for those Americans for whom it is recommended to receive the seasonal influenza vaccine. No vaccine is 100 percent effective against preventing disease, but vaccination is the best protection against influenza and can prevent many illnesses and deaths.

“'The approval of this year’s seasonal influenza vaccine is an example of the FDA’s important responsibility to assure timely availability of vaccine to help protect the health of the American public,’ said Margaret A. Hamburg, M.D., commissioner of food and drugs. ‘A new seasonal influenza vaccine each year is a critical tool in protecting public health.’

The six vaccine brand names and manufacturers are: Afluria, CSL Limited; Fluarix, GlaxoSmithKline Biologicals; FluLaval, ID Biomedical Corporation; Fluvirin, Novartis Vaccines and Diagnostics Limited; Fluzone, Sanofi Pasteur Inc.; and FluMist, MedImmune Vaccines Inc.

Each year, experts from the FDA, WHO, U.S. Centers for Disease Control and Prevention (CDC), and other institutions study virus samples and patterns collected from around the world in an effort to identify strains that may cause the most illness in the upcoming season.

Based on those forecasts and on the recommendations of the FDA’s Vaccine and Related Products Advisory Committee, the FDA determines the three strains that manufacturers should include in their vaccines for the U.S. population. The closer the match between the circulating strains and the strains in the vaccine, the better the protection against the disease.

The vaccine for the 2009-2010 seasonal influenza contains:

- an A/Brisbane/59/2007 (H1N1)-like virus
- an A/Brisbane/10/2007 (H3N2)-like virus
- a B/Brisbane/60/2008-like virus

There is always a possibility of a less than optimal match between the virus strains predicted to circulate and the virus strains that end up causing the most illness. Even if the vaccine and the circulating strains are not an exact match, the vaccine may reduce the severity of the illness or may help prevent influenza-related complications.
According to the CDC, between 5 percent and 20 percent of the U.S. population develops influenza each year. More than 200,000 are hospitalized from its complications and about 36,000 people die. Older people, young children, and people with chronic medical conditions are at higher risk for influenza-related complications. Vaccination of these groups is critical.

Additionally, influenza immunization of health care personnel is important in protecting them and others from influenza.

For more information:

FDA Web Page on Influenza Vaccine Safety & Availability

FDA List of Strains Included in the 2009-2010 Influenza Vaccine
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm162050.htm

U.S. Centers for Disease Control and Prevention Web Page on Seasonal Influenza Resources for Health Professionals
http://www.cdc.gov/flu/professionals/vaccination/

U.S. Centers for Disease Control and Prevention Web Page with Key Fact About Seasonal Flu Vaccine
http://www.cdc.gov/flu/protect/keyfacts.htm