Association Bulletin #03-13

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To: AABB Members

From: Roger Y. Dodd, PhD, President
Karen Shoos Lipton, JD, Chief Executive Officer

Re: Intranasal Flu Vaccine - FluMist™

Summary
In June 2003, the Food and Drug Administration (FDA) approved FluMist™, an influenza vaccine that is the first nasally administered vaccine to be marketed in the United States. It is also the first live virus influenza vaccine approved in the United States. This Association Bulletin summarizes information regarding the intranasal vaccine and provides recommendations on donor acceptability.

Background
FluMist™ is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5-17 years of age, and healthy adults, 18-49 years of age. Immunization of immune-compromised individuals and their close contacts is contraindicated.

FluMist™ is a combination of three live-attenuated influenza virus reassortants of the strains recommended by the U.S. Public Health Service for the 2003-2004 season. These strains are *cold-adapted* (i.e., they replicate efficiently at 25ºC, approximating intranasal temperatures); *temperature-sensitive* [i.e., they are restricted in replication at 37ºC (Type B strains) or 39ºC (Type A strains), temperatures at which many wild-type influenza viruses grow efficiently]; and *attenuated* so as not to produce classic influenza-like illness in the ferret model of human influenza infection. The cumulative effect is that the vaccine viruses replicate in the nasopharynx to produce protective immunity. In studies in children (8-36 months), the vaccine viruses were transmitted from immunized individuals to direct contacts up to three weeks after immunization. This transmission is presumed to be by airborne and direct contact routes, similar to the transmission of wild-type influenza. The frequency and duration of shedding FluMist™ viral strains by individuals 5-49 years of age has not been established.

The AABB Transfusion Transmitted Diseases (TTD) committee evaluated the data currently available on FluMist™.

1. The vaccine strains' growth is restricted at core body temperature.
2. Attenuation of the vaccine with respect to disease causation has been studied in clinical trials with more than 20,000 vaccinated persons.

3. Transfusion transmission of wild-type, fully virulent, influenza viruses (which can cause viremia) has not been demonstrated.
4. Persons having close contact with influenza-infected individuals may be incubating the disease; however, these persons have not been deferred.

Recommendations

On the basis of this evaluation and the resulting recommendation of the TTD committee, the AABB is currently recommending that donors not be deferred after receipt of FluMist™. Additionally, the AABB requested review of this position by personnel at the FDA Office of Blood Research and Review, Center for Biologics Evaluation and Research, and they have agreed with this recommendation.