Refrigerated FluMist FDA-Approved for Ages 5-49

BY HEIDI SPLETE
Senior Writer

A new formulation of intranasal influenza live virus vaccine that can be stored in a standard refrigerator, rather than kept frozen, has been approved by the Food and Drug Administration.

The new formulation of the trivalent vaccine, FluMist, is approved for healthy children and adults aged 5-49 years, and it will be available for the 2007-2008 flu season, according to a statement from the vaccine's manufacturer, MedImmune Inc. The company is seeking FDA approval of the refrigerated vaccine for use in children aged 12-59 months (1-5 years).

"This is a useful advance because the vaccine can be stored more easily and implemented better," Dr. Sarah Long, chief of the infectious diseases section at St. Christopher's Hospital for Children, Philadelphia, said in an interview.

But the new formulation's effect on physician practices will not necessarily be substantial at this time, added Dr. Long, who is also a member of the American Academy of Pediatrics' Red Book Committee.

"It will be very useful if it is approved for [younger] children," she noted.

The refrigerated formulation of FluMist will likely be appealing because of its ease of use, but the major factors driving influenza vaccination rates in primary care offices will continue to be cost (including reimbursement), vaccine supply and distribution, efficacy, and safety concerns, Dr. Jonathan Temte, of the University of Wisconsin, Madison, said in an interview.

"FluMist appears to have had better supply and distribution characteristics than the other influenza vaccines of late, but it is hampered by a higher price," said Dr. Temte, who also serves as American Academy of Family Physicians' liaison to the Center for Disease Control and Prevention's Advisory Committee on Immunization Practices.

That said, data have shown good efficacy for FluMist even in years when the vaccine was not well matched to the flu virus, he added.

Compared with injectable vaccine, FluMist provides better, longer lasting immunity and better cross-protection from year to year as the flu virus drifts, said Dr. Michael Pichichero, a private practice pediatrician and professor of microbiology and immunology at the University of Rochester (N.Y.). But the biggest drawback is cost. "Refrigeration is a minor advance in my opinion. If it were the same cost, it would be a no-brainer," he said.

The high cost will continue to be a major impediment to FluMist's utilization, although the new formulation would help to ensure a steadier vaccine supply.

Should universal influenza vaccination be recommended, the new FluMist formulation would theoretically make that goal more feasible. Most people are not willing to line up for an injection each year. At the same time, the refrigerated formulation broadens the potential for flu immunizations to be offered in locations outside of the physician's office, such as schools or clinics. But the caveat is that FluMist of either formulation can be given only to persons who are otherwise healthy, Dr. Long said.

The high cost will continue to be a major impediment to FluMist's utilization, although the new formulation would help to ensure a steadier vaccine supply if universal vaccination is advised, Dr. Temte added.

The original FluMist, which is also manufactured by MedImmune, has been available in a frozen formulation since its FDA approval in 2003. ■

Feds Launch AIDS Searchable Web Site

The U.S. Department of Health and Human Services has launched AIDS.gov, a searchable Web site for the public.

The site provides information on HIV and AIDS research programs, prevention, testing, treatment, and federal policies and resources. The site also has links to information on federal funding and financial assistance for AIDS organizations. For more information, visit www.aids.gov. ■