

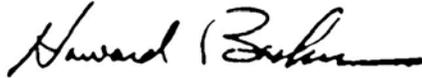


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Director

State of California—Health and Human Services Agency
California Department of Public Health



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Governor

DATE: September 14, 2007 IZB-FY0708-03
TO: Public and Private Sector Vaccines for Children (VFC) Providers
FROM: Howard Backer, M.D., M.P.H., Chief Immunization Branch 
SUBJECT: Influenza Vaccine Availability for VFC Children; and VFC Vaccine Order Form, CDPH IMM 376F

This memo is divided into sections to enable you to quickly access the information you need:

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SUMMARY

- On June 29, 2007, the federal Advisory Committee on Immunization Practices (ACIP) published its annual **Influenza Recommendations (MMWR, June 29, 2007 / 56(Early Release); 1-54)**, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e629a1.htm>. The Vaccines for Children (VFC) Program Influenza Resolution for this current flu season can also be found online at: <http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0207influenza.pdf>.
- The 2007 recommendations for pediatric influenza vaccination emphasize the importance of administering two doses of influenza vaccine to all previously unvaccinated children aged 6 months to 8 years. The ACIP has also recommended that children aged 6 months-8 years who received only one dose in their first year of vaccination receive two doses the following year, with single annual doses in subsequent years. Providers are also encouraged to continue to offer influenza vaccines throughout influenza season.

- Due to a limited supply of preservative-free influenza formulation, preservative-free vaccines should be reserved for administration to VFC-eligible children younger than three years of age and pregnant teens under 18 years of age. According to the California Mercury Free Act of 2004, which took effect July 1, 2006, pregnant women or children younger than three years old may only receive vaccine doses that contain trace levels or no mercury. [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)].
- Beginning September 14, 2007, the California VFC Program will accept influenza vaccine orders for the 2007-2008 influenza season. Providers are encouraged to submit their initial vaccine order, and submit subsequent supplemental orders throughout the season. Orders will continue to be filled as supply permits.
- It is anticipated that the age recommendation for the use of Live, Attenuated Influenza Vaccine (LAIV) in healthy children will be expanded to children 2 to 5 years, pending approval by Food and Drug Administration (FDA) this fall. If approved, ACIP will vote to include the expansion of age eligibility in this year's recommendation. A supplemental communication will be issued to VFC providers if it occurs.
- The enclosed 2007-2008 "Influenza Season Vaccine Order Form" must be used when placing influenza vaccine orders. This year's form includes available products for this year's influenza season. Orders submitted prior to this notification must be re-submitted utilizing the updated order form.
- An initial supply of influenza vaccine is expected from vaccine manufacturers by late September, with multiple subsequent shipments expected throughout October-November. Therefore, providers should be prepared to receive a portion of their request initially and will need to submit additional orders throughout the season, as necessary. **The VFC Program will notify providers when vaccine delivery begins.**

2007-2008 INFLUENZA VACCINE COMPOSITION

Both inactivated and live, attenuated influenza vaccines for use in the 2007–2008 U.S. influenza season includes the following influenza virus strains:

- A/Solomon Islands/3/2006 (H1N1)-like (new for this season);
- A/Wisconsin/67/2005 (H3N2)-like; and
- B/Malaysia/2506/2004-like antigens.

These viruses will be used because they are representative of influenza viruses that are anticipated to circulate in the United States during the 2007-2008 influenza season. Both types of vaccines are grown in eggs.

AVAILABLE INFLUENZA VACCINES

The VFC Program will make available a variety of approved influenza vaccine products for immunization of VFC-eligible children 6 months to 18 years of age during the 2007-2008 influenza season. Please refer to the attached "Approved Influenza Vaccine Products" chart for

a detailed description of available products, presentation, formulation, and recommended ages for use.

Available products:

Children ages 6-35 months

- Fluzone[®] (sanofi), No Preservative: Pediatric Dose (children 6-35 months of age)

Children ages 3-18 years

- Fluzone[®] (sanofi), Preservative-containing (children and adolescents aged 3-18 years)
- Fluvirin[®] (Novartis), Preservative-containing (children and adolescents aged 4-18 years)
- FluMist[®] (MedImmune), Preservative-free, Live Attenuated Influenza Vaccine (LAIV), (healthy children and adolescents aged 5-18 years of age only)

Pregnant women through 18 years of age

- Fluzone[®] (sanofi), No Preservative (adolescent women, through 18 years of age)

ELIGIBILITY FOR VFC-SUPPLIED INFLUENZA VACCINE

Influenza vaccine supplied by VFC may be used for all VFC-eligible children in the following ACIP recommended groups:

Eligible Groups for Trivalent Inactivated Influenza Vaccine (TIV)

- All children aged 6-59 months.
- Children and adolescents aged 5 through 18 years who:
 - Have chronic disorders of the pulmonary or cardiovascular systems, including asthma.
 - Have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]).
 - Have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration.
 - Are receiving long-term aspirin therapy and may therefore be at risk for developing Reye syndrome after influenza.
 - Are residents of nursing homes and other chronic-care facilities that house persons at any age who have chronic medical conditions.
- Adolescent females aged < 19 years who will be pregnant during influenza season.
- Children and adolescents aged 5 through 18 years who are household contacts of persons in the following high-risk groups:
 - any children less than five years old;
 - children or adolescents in any of the other groups listed above;
 - any person 50 years of age or older;
 - adults with chronic disorders of the pulmonary or cardiovascular systems;

- adults who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by HIV).

Eligible Groups for Live Attenuated Influenza Vaccine (LAIV)

- All healthy children and adolescents aged 5 years through 18 years with priority given to:
- Children and adolescents aged 5 through 18 years who are household contacts of persons in the following high-risk groups, provided that the contacts are not severely immunocompromised (e.g., patients with hematopoietic stem cell transplants) and require care in a protective environment:
 - any child less than five years old;
 - children or adolescents in any of the other groups listed above;
 - any person 50 years or older;
 - adults with chronic disorders of the pulmonary or cardiovascular systems;
 - adults who have required regular medical follow-up or hospitalization during the preceding year for chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by HIV).

Note: It is anticipated that the age recommendation for the use of LAIV in healthy children will be expanded to children 2 to 5 years, pending approval by the FDA in the fall of 2007. If approved, ACIP will vote to include the expansion of age eligibility in this year's recommendation. A supplemental communication will be issued to VFC providers if it occurs.

DOSAGE AND ADMINISTRATION

Trivalent Inactivated Influenza Vaccine (TIV)

Children under nine years of age receiving inactivated influenza vaccine for the first time require two doses, one month apart.

- For children 6 through 35 months of age, one dose is equivalent to 0.25 mL.
- For children > 35 months of age, one dose is equivalent to 0.5 mL.

Children under nine years of age who received only **one** dose of influenza vaccine during a prior season are recommended to receive **two** doses this season.

Children *under* three years of age should receive preservative-free influenza products.

Inactivated influenza vaccine should be administered intramuscularly in the anterolateral aspect of the thigh for infants and young children. Adults and older children should be vaccinated in the deltoid muscle.

Live, Attenuated Influenza Vaccine (LAIV)

Children aged five to nine years previously unvaccinated who are receiving Live, Attenuated Influenza Vaccine (LAIV) should receive two doses of LAIV separated by 6-10 weeks.

Children under nine years who received **only one** dose of any influenza vaccine in the past are

also recommended to receive two doses this season. The TIV and LAIV vaccines are considered interchangeable in a series or from year to year.

The LAIV vaccine is only administered intranasally. In January of this year, a new refrigerator-stable formulation of LAIV (also sold under the brand name of FluMist[®]) was licensed by FDA. The new formulation will be supplied in pre-filled, single-use sprayers containing 0.2 mL of vaccine. One half of the sprayer's contents (.10 mL) should be sprayed into each nostril while the patient is in an upright position. Do not repeat a dose if the patient sneezes after administration of the dose. There is no need to thaw the vaccine prior to administration.

Please note that LAIV products received early in the flu season may have an expiration date of January 2008. Please take this into account when placing initial orders of this product.

STORAGE AND HANDLING OF INFLUENZA VACCINES

Both Trivalent Inactivated Vaccine (TIV) and Live, Attenuated Influenza Vaccine (LAIV), 2007-2008 New Formulation, should be **refrigerated** at a temperature range of 35° to 46°F (2° to 8°C), with a preferred temperature of 40°F. **Do not freeze** or expose these vaccines to freezing temperatures.

Please make sure that vaccine orders are placed according to your refrigerator's storage capacity, as you will be storing all received flu vaccines in your refrigerator, along with all of your regular pediatric vaccines.

Influenza vaccines will be shipped to your practice directly from VFC's distributor, McKesson Specialty Inc., in insulated containers maintaining a constant temperature between 35° to 46°F (2° to 8°C). Immediately upon receipt, verify that the shipment's temperature monitor screen indicates "OK" to ensure the temperature has been maintained while shipment was in transit to your practice. Also, carefully verify that the requested vaccine doses have been received and match the doses reflected in your shipment's packing slip. Please refrigerate your influenza vaccine immediately.

Please contact the VFC Program **immediately** to report any discrepancy in your order or if the vaccine shipment's monitor indicate "Not OK." Please instruct clinic staff to label the vaccines "Do not use" and refrigerate the vaccines until you have received further instructions from the VFC Program.

ORDERING INSTRUCTIONS

The enclosed copy of the **2007-2008 VFC Influenza Vaccine Order Form**, CDPH 8501F (8/07), **must** be used when placing influenza vaccine orders. The order form includes a variety of different products available for the 2007-2008 influenza season. Please retain a copy of submitted orders for your records to assist you in placing future orders. You may fax your completed influenza vaccine order to 1-877-329-9832 (877-FAXX-VFC). In order to avoid unnecessary delays in the processing of your influenza vaccine order, please make sure to follow these steps:

September 14, 2007

- a. Submit your influenza order utilizing the new VFC Influenza Vaccine Order Form, CDPH 8501 F (8/07). **Please do not utilize any other VFC order form to place your vaccine order.** The 2007-2008 product availability is listed in this year's form and may differ from previous years.
- b. If you have placed an influenza vaccine order prior to September 14, 2007, please resubmit your order utilizing the new form.
- c. Orders will be placed in a "Back Order" listing until vaccine inventories are received from manufacturers at the VFC Program distributor. The VFC Program will notify providers as soon as inventories of influenza vaccine are received and approved vaccine orders begin to be shipped.
- d. Please estimate your initial vaccine order based on influenza vaccine doses received during the 2006-2007 season. When placing your order, request sufficient influenza vaccine to vaccinate healthy VFC-eligible children 6 to 59 months of age in your practice, as well as high-risk children 5 to 18 years of age. Please note that influenza vaccine orders will be approved according to your practice's profile estimates and estimate of the proportion of children you will vaccinate.
- e. Because influenza vaccine comes in multiple shipments, most providers can expect to receive only a portion of their initial order so that we can ensure that all VFC providers receive a supply early in the season. **Please submit subsequent supplemental vaccine orders throughout the influenza season as needed. The VFC Program will continue to ship vaccines as long as our inventory and national supplies last.** Unlike all other pediatric vaccines, influenza vaccine supplemental orders may be submitted at any time. You may submit supplemental orders outside of your assigned vaccine ordering frequency.
- f. Ensure that your refrigerator's capacity is sufficient to accommodate vaccine doses ordered. Keep in mind that LAIV's new formulation requires storage in your refrigerator along with the rest of the influenza vaccine products ordered and your routine supply of all pediatric vaccines.

BILLING NOTES

Medi-Cal: To bill Medi-Cal for vaccines and administration of influenza vaccines, use CPT-4 codes 90655-90658 (TIV) and 90660 (LAIV). In addition, the **-SK (high risk) modifier must** be used for all influenza vaccines, including LAIV; document your patient's high-priority category in the patient's medical record (not on the claim form). If VFC vaccine is used, the provider will only be reimbursed for the administration fee.

Child Health and Disability Prevention Program (CHDP): The CHDP program will reimburse for influenza vaccine and its administration:

- If influenza vaccine is provided by the VFC Program use code "53."
- The provider must indicate "high risk factor" in the "Comments/Problems" box for code numbers 53 and 54 when used for influenza vaccine administered.
- If Live Attenuated Influenza Vaccine (LAIV), intranasally administered is provided by the VFC Program use code "71."

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- Code 71 is payable for ages 5 years through 18 years, 11 months, administration fee only. Nothing is required in the "Comments/Problems" box.

RETURN OF UNUSED VIALS OF INFLUENZA VACCINE

Vaccines for Children providers must return all expired or spoiled influenza vaccine (including vials, syringes, and nasal sprayer packages) to VFC's national vaccine distributor, McKesson Specialty. Please keep in mind McKesson does not accept viable vaccine returns directly from VFC providers.

Complete a VFC Return and Transfer Form and make a copy for your records. Fax a copy to the VFC Program at 877-FAXX-VFC (877-329-9832) and enclose the original copy of the form in the package with the non-viable or expired vaccines you are returning to the VFC program. Return vaccines to:

McKesson Specialty Distribution
4853 Crumpler Road
Memphis, TN 38141
Attn: Eric Doss/ Tommy McRae

When returning your vaccines, please use a postage-paid container in which you receive your normal vaccine shipments, and clearly label the outside of the shipping container "Non-Viable Vaccine Enclosed."

VIS STATEMENTS

Copies of the current interim Vaccine Information Statement (VIS) for the Inactivated Influenza Vaccine and the Live, Attenuated Influenza Vaccine (LAIV), dated 07/16/2007, are included in this mailing and are also at <http://www.cdc.gov/nip/publications/VIS/default.htm>. Federal regulation requires that you provide the VIS to a parent or guardian before the child receives influenza vaccine.

HELPFUL RESOURCES

To help you remind parents about new pediatric flu shots recommendations, we are enclosing a copy of the "***Guess Who Needs a Flu Shot***" (IMM-782) self-adhering cling-on flyer. This piece is suitable for posting in a medical office waiting room or patient exam room and requires no tape or thumb tacks. In addition, a sample "***Guess Who Needs a Flu Shot***" (IMM-781) reminder postcard is enclosed. To order additional copies of these materials, VFC providers should contact their local health department. Listings are at <http://www.dhs.ca.gov/ps/dcdc/izgroup/pdf/lhdlist.pdf>.

QUESTIONS?

If you have any questions, please call your VFC Field Representative or the VFC Program at: 877-243-8832 (877-2GET-VFC).

Enclosures - Inactivated Influenza Vaccine Information Statement (7/16/07)
Live Intranasal Influenza Vaccine Information Statement (7/16/07)
VFC Vaccine Order Form, CDPH 8501 F (8/07)
2007-2008 VFC Flu Product Guide
"Guess Who Needs a Flu Shot" postcard (IMM-781)
"Guess Who Needs a Flu Shot" cling-on flyer (IMM-782)

cc: CDPH Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors
Vanessa Baird, Chief, Medi-Cal Managed Care Division, CDPH
Marian Dalsey, M.D., Chief, Children Medical Services Branch, CDPH
Michael Farber, M.D., Chief Medical Officer, Medi-Cal Managed Care, CDPH
Susann Steinberg, M.D., Chief, Maternal, Child and Adolescent Health/Office of
Family Planning Branches, CDPH
Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB
Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDPH
Kathy Chance, M.D., Children Medical Services Branch, CDPH

VACCINES FOR CHILDREN (VFC) PROGRAM 2007-08 INFLUENZA VACCINE ORDER FORM

FAX TO: (877) 329-9832

DATE		VFC PIN NUMBER (6 digit)	
NAME OF PHYSICIAN'S OFFICE, PRACTICE, CLINIC, ETC.		CONTACT PERSON	
DELIVERY ADDRESS (Number and Street—No P.O. Boxes)		<input type="checkbox"/> CHECK HERE IF THIS IS A NEW ADDRESS.	CITY
			ZIP CODE
TELEPHONE:	FAX:	EMAIL:	COUNTY:

DELIVERY: Check all days and times you may receive vaccine. If closed during lunch hour, please specify.	Tue:	From:	to:	(Closed for lunch from:	to:
	Wed:	From:	to:	(Closed for lunch from:	to:
	Thur:	From:	to:	(Closed for lunch from:	to:
	Fri:	From:	to:	(Closed for lunch from:	to:
	STORAGE CAPACITY (Check All That Apply) <input type="checkbox"/> Small Unit/Under the Counter Refrigerator: # of units _____ <input type="checkbox"/> Refrigerator/Freezer Combination: # of units _____ <input type="checkbox"/> Stand alone freezer: # of units _____ <input type="checkbox"/> Commercial/Laboratory Grade Unit: # of units _____				

Please complete all sections on this order form in order for VFC to process your vaccine order.

AVAILABLE THROUGHOUT FLU SEASON AS SUPPLY PERMITS							
AGE GROUPS	DOSES USED	VACCINE INVENTORY (DOSES ON HAND)			NEW VACCINE ORDER		
	Number of doses used since last order. Enter "0" if none	Number of doses on hand (Current Inventory)	Lot Number	Expiration Date	Doses Requested (Multiples of 10)	Product and Presentation (Please mark your product preference. Note: product may be substituted if preferred choice is not available.)	
ALL PRODUCTS MUST BE REFRIGERATED AT A TEMPERATURE BETWEEN 35° - 46° F. DO NOT FREEZE ANY OF THESE VACCINES!							
Children 6-35 months of age					_____doses	Fluzone® No preservative, pediatric dose	0.25 mL single-dose syringe 10 doses per box
Children 36 months-18 years of age <small>Note: Age indications for products available for this age range differ.</small>					_____doses	<input type="checkbox"/> Fluzone® (Ages 3-18 years)	5.0 mL multi-dose vial 10 doses per vial
					_____doses	<input type="checkbox"/> Fluvirin® (Ages 4-18 years)	5.0 mL multi-dose vial 10 doses per vial
Healthy Children 5-18 years of age					_____doses <small>(Minimum order 20 doses, multiples of 10)</small>	FluMist® (Live Attenuated Influenza Vaccine, LAIV)	0.20 mL Nose sprayer 10 doses per box
Pregnant Teens under 19 years of age					_____doses	<input type="checkbox"/> Fluzone® No Preservative	0.5 mL single-dose vials 10 doses per box
					_____doses	<input type="checkbox"/> Fluzone® No Preservative	0.5 mL single-dose syringe 10 doses per box

IMPORTANT: IF YOUR VACCINE BRAND CHOICE AND PACKAGING IS NOT AVAILABLE PRODUCT MAY BE SUBSTITUTED.

In order to ensure that your vaccine order is processed as quickly as possible, the VFC Vaccine Order form **must** be completely filled out. Fill in all blank sections of the form. Orders submitted in outdated forms may delay the processing of your vaccine order. See back page for instructions.

2007-2008 Influenza vaccine orders received prior to the receipt of vaccine supplies at VFC national distributor will remain on hold until product is available.





Instructions for Completing the VFC Influenza Vaccine Order Form

1. Enter your clinic's PIN number.

The PIN number is the six-digit Provider Identification Number assigned to your clinic upon enrolling in the VFC Program. (This is not your medical license or CHDP/Medi-Cal provider numbers). You may contact the VFC Office at (877) 243-8832 to obtain your PIN.

2. Use the same facility name that is on record with the VFC Program.

The facility name on record can be found on the packing slips that accompany your vaccine shipments. Do not change this VFC facility name without first notifying the VFC Program in writing, even if the clinic name has changed or is incorrect.

3. Specify vaccine delivery address.

This is the address the VFC Program will provide to VFC's national vaccine distributor, McKesson Specialty, to deliver vaccines to your site. Check the appropriate box on the order form if this is a new address. (Remember to include a letter regarding the change of address with your vaccine order.)

4. Specify current days and times during which you can receive delivery of VFC vaccines.

McKesson Specialty delivers vaccine Tuesday through Friday only. When specifying delivery times, take into account times of the day during which you cannot receive deliveries of VFC vaccine (e.g., lunch).

5. Check the appropriate box that best describe your refrigerator unit (s).

When placing your flu vaccine order, please make sure you have enough storage space in your refrigerator to accommodate your flu vaccine shipment along with all of your regular pediatric vaccines. Remember: All influenza products available, including FluMist®, must be refrigerated.

6. Select product choice and indicate doses requested.

Influenza vaccine products should be appropriately selected based on the age range of patients served by your clinic. Please select only one product or presentation within each age group when multiple choices are available. The number of doses requested must be in multiples of 10, since most products are shipped in packages of 10 single dose vials/syringes or 10-dose multi-dose vials.

7. For supplemental influenza orders, record usage of all VFC influenza vaccines administered since your previous or initial order.

For your *initial* order during the 2007–2008 flu season, enter -0- in the "Usage" section. Please do not record usage of vaccines administered during the previous flu season. Subsequent influenza vaccine orders must include the number of doses administered since your previous order. This Information may be easily obtained from a usage log or an Immunization Registry-generated usage report.

8. For supplemental influenza orders, list current influenza vaccine inventory of VFC supplied flu vaccines.

For your *initial* order during the 2007–2008 Flu season, enter -0- in the "Inventory" section. Subsequent influenza vaccine orders must include a listing of vaccines remaining in your inventory since your previous order, and their corresponding lot numbers, and expiration dates. You may use a separate sheet of paper to record additional lot numbers if needed. You may also attach a registry-generated inventory report outlining detailed information on lot numbers and expiration dates. However, you must still record the total number of doses on-hand in the order form. This will assist VFC Customer Service Representatives in approving your vaccine order in a timely manner.

9. Return any expired or spoiled flu vaccines to VFC's national vaccine distributor.

All expired or spoiled influenza vaccine (including vials, syringes, and nasal sprayer packages) must be returned to the VFC Program's distributor. Return products to: **McKesson Specialty Distribution, 4853 Crumpler Road, Memphis, TN 38141.**

When Completed:

Fax to: (877) 329-9832 (toll-free)

OR

Mail to: Vaccines for Children Program
California Department of Public Health,
Immunization Branch
850 Marina Bay Parkway Building P, 2nd Floor
Richmond, CA 94804

Always keep a copy for your records!

For Questions Call: (877) 243-8832

OR

Contact your local VFC Representative



Vaccines for Children (VFC) Program

2007-2008 Influenza Vaccine Product Guide

Vaccine	Age	Available Products & Manufacturer	Thimerosal Free*	Formulation	Age Indication^	VFC Age Eligibility	Number of Doses
Trivalent Inactivated Vaccine (TIV)	Children 6–35 months of age	Fluzone® Pediatric Dose No Preservative, Sanofi	Yes	10 pack - single dose pre-filled syringe, 0.25 mL	6–35 months	6–35 months	1 or 2 doses ¹ (recommended dosage 0.25 mL)
	Children 3–18 years of age	Fluzone®, Sanofi	No	10 doses- Multi-dose vial, 5 mL	>6 months	3–18 years	1 or 2 doses ¹ (recommended dosage 0.50 mL)
		Fluvirin®, Novartis			> 4 years	4–18 years	
	Pregnant teens under 18 years of age	Fluzone® No Preservative, Sanofi	Yes	10 pack- single dose pre-filled syringe, 0.5 mL	> 36 months	Pregnant teens under 18 years of age.	1 dose
10 pack - single dose vial, 0.5 mL							
Live, Attenuated Influenza Vaccine (LAIV)	Healthy Children 5–18 years of age Note: May be licensed for younger ages in Fall, 2007	FluMist®, MedImmune	Yes	10 pack- Single dose² intranasal sprayer, 0.20 mL	Healthy children 5-49 years	5–18 years	1 or 2 doses ³ (recommended dosage 0.20 mL)

* Effective July 1, 2006, pregnant women or children younger than three years old may only receive influenza vaccine doses that contain < 1.0 micrograms per 0.5 milliliter dose. [Health and Safety (H&S) Code Section 124172, Chapter 837, Statutes of 2004 (AB 2943, Pavley)].

^ Age indication for product use differs from VFC's age eligibility. Product must be administered according to VFC age eligibility.

¹Two doses administered > 1 month apart are recommended for children 6 months-9 years receiving influenza vaccine for the first time. If the child received only a single, first-ever dose last season, then 2 doses should be administered this season.

² One dose equals 0.20 mL divided equally between each nostril.

³Two doses administered at least 6 weeks apart are recommended for children <9 years of age receiving influenza vaccine for the first time. If the child received only a single, first-ever dose last season, then 2 doses should be administered this season.

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2007-08

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which spreads from infected persons to the nose or throat of others.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die – mostly elderly.

Influenza vaccine can prevent influenza.

2 Inactivated Influenza vaccine

There are two types of influenza vaccine:

Inactivated (killed) vaccine, or the “flu shot” is given by injection into the muscle.

Live, attenuated (weakened) influenza vaccine, called LAIV, is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

For most people influenza vaccine prevents serious influenza-related illness. But it will *not* prevent “influenza-like” illnesses caused by other viruses.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended. Protection lasts up to a year.

It takes up to 2 weeks for protection to develop after the vaccination.

Some inactivated influenza vaccine contains thimerosal, a preservative that contains mercury. Some people believe thimerosal may be related to developmental problems in children. In 2004 the Institute of Medicine published a report concluding that, based on scientific studies, there is no evidence of such a relationship. If you are concerned about thimerosal, ask your doctor about thimerosal-free influenza vaccine.

3 Who should get inactivated influenza vaccine?

People 6 months of age and older can receive inactivated influenza vaccine. It is recommended for **anyone who is at risk of complications from influenza or more likely to require medical care:**

- **All children** from 6 months up to 5 years of age.
- Anyone **50 years of age or older.**
- Anyone 6 months to 18 years of age on **long-term aspirin treatment** (they could develop Reye Syndrome if they got influenza).
- Women who will be **pregnant** during influenza season.
- Anyone with **long-term health problems** with:
 - heart disease
 - kidney disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with a **weakened immune system** due to:
 - HIV/AIDS or other diseases affecting the immune system
 - long-term treatment with drugs such as steroids
 - cancer treatment with x-rays or drugs
- Anyone with certain **muscle or nerve disorders** (such as seizure disorders or severe cerebral palsy) that can lead to breathing or swallowing problems.
- **Residents of nursing homes and other chronic-care facilities.**

Influenza vaccine is also recommended for anyone who lives with or cares for people at high risk for influenza-related complications:

- **Health care providers.**
- **Household contacts and caregivers of children** from birth up to 5 years of age.
- **Household contacts and caregivers** of people 50 years and older, and those with medical conditions that put them at higher risk for severe complications from influenza.

A yearly influenza vaccination should be *considered* for:

- People who provide **essential community services.**
- People living in **dormitories** or under other crowded conditions, to prevent outbreaks.
- People at high risk of influenza complications who **travel** to the Southern hemisphere between April and September, or to the tropics or in organized tourist groups at any time.

Influenza vaccine is also recommended for anyone who wants to **reduce the likelihood of becoming ill** with influenza or **spreading influenza to others.**

4

When should I get influenza vaccine?

Plan to get influenza vaccine in October or November if you can. But getting vaccinated in December, or even later, will still be beneficial in most years. You can get the vaccine as soon as it is available, and for as long as illness is occurring. Influenza illness can occur any time from November through May. Most cases usually occur in January or February.

Most people need one dose of influenza vaccine each year. **Children younger than 9 years of age getting influenza vaccine for the first time** should get 2 doses. For inactivated vaccine, these doses should be given at least 4 weeks apart.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

5

Some people should talk with a doctor before getting influenza vaccine

Some people should not get inactivated influenza vaccine or should wait before getting it.

- Tell your doctor if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.
 - Influenza vaccine virus is grown in eggs. People with a severe egg allergy should not get the vaccine.
 - A severe allergy to any vaccine component is also a reason to not get the vaccine.
 - If you have had a severe reaction after a previous dose of influenza vaccine, tell your doctor.
- Tell your doctor if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). You may be able to get the vaccine, but your doctor should help you make the decision.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a **mild illness** can usually get the vaccine.

6

What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- fever • aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a certain type of influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

7

What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

Call a doctor, or get the person to a doctor right away.

- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

8

The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

9

How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO)
 - Visit CDC's website at www.cdc.gov/flu



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2007-08

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which spreads from infected persons to the nose or throat of others.

Other illnesses can have the same symptoms and are often mistaken for influenza. But only an illness caused by the influenza virus is really influenza.

Anyone can get influenza, but rates of infection are highest among children. For most people, it lasts only a few days. It can cause:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Some people get much sicker. Influenza can lead to pneumonia and can be dangerous for people with heart or breathing conditions. It can cause high fever and seizures in children. On average, 226,000 people are hospitalized every year because of influenza and 36,000 die – mostly elderly.

Influenza vaccine can prevent influenza.

2 Live, attenuated influenza vaccine (nasal spray)

There are two types of influenza vaccine:

Live, attenuated influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils rather than injected into the muscle.

Inactivated influenza vaccine, sometimes called the “flu shot,” is given by injection. *This vaccine is described in a separate Vaccine Information Statement.*

For most people influenza vaccine prevents serious influenza-related illness. But it will *not* prevent “influenza-like” illnesses caused by other viruses.

Influenza viruses are always changing. Because of this, influenza vaccines are updated every year, and an annual vaccination is recommended. Protection lasts up to a year.

It takes up to 2 weeks for protection to develop after vaccination.

LAIV does not contain thimerosal or other preservatives.

3 Who can get LAIV?

Live, intranasal influenza vaccine is approved for **healthy people from 5 through 49 years of age**, who are not pregnant. This includes people who can spread influenza to others at high risk, such as:

- **Household contacts and out-of-home caregivers** of children from birth to 5 years of age.
- Physicians and nurses, and family members or any one else in **close contact with people at risk** of serious influenza.

Influenza vaccine should be given to anyone who wants to **reduce the likelihood of becoming ill** with influenza or **spreading influenza to others**.

LAIV may be considered for:

- People who provide **essential community services**.
- People living in **dormitories** or under other crowded conditions, to prevent outbreaks.

4 Who should *not* get LAIV?

LAIV is not licensed for everyone. The following people should check with their health-care provider about getting the **inactivated** vaccine (flu shot).

- **Adults 50 years of age and older** or **children 6 months up to 5 years of age**. (Children younger than 6 month cannot get *either* influenza vaccine.)
- People who have **long-term health problems** with:
 - heart disease
 - kidney disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with a **weakened immune system**.
- Children or adolescents on **long-term aspirin treatment**.
- **Pregnant women**.
- Anyone with a history of **Guillain-Barré syndrome** (a severe paralytic illness, also called GBS).

Inactivated influenza vaccine is the preferred vaccine for people (including health-care workers, and family members) coming in **close contact with anyone who has a severely weakened immune system** (that is, anyone who requires care in a protected environment).

Some people should talk with a doctor before getting *either* influenza vaccine:

- Anyone who has ever had a **serious** allergic reaction to **eggs** or another vaccine component, or to a **previous dose** of influenza vaccine.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your doctor or nurse about whether to reschedule the vaccination. People with a **mild illness** can usually get the vaccine.

5 When should I get influenza vaccine?

Plan to get influenza vaccine in October or November if you can. But getting vaccinated in December, or even later, will still be beneficial in most years. You can get the vaccine as soon as it is available, and for as long as illness is occurring. Influenza illness can occur any time from November through May. Most cases usually occur in January or February.

Most people need one dose of influenza vaccine each year. **Children younger than 9 years of age getting influenza vaccine for the first time** should get 2 doses. For LAIV, these doses should be given 6-10 weeks apart.

LAIV may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine *can* cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 5-17 years of age have reported mild reactions, including:

- runny nose, nasal congestion or cough
- headache and muscle aches
- fever
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

These symptoms did not last long and went away on their own. Although they can occur after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.

- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Over six million doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

7 What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement
Live, Attenuated Influenza Vaccine (7/16/07) 42 U.S.C. §300aa-26

Guess who needs a flu shot?



**Your
Child.**

Flu shots are recommended for children **6 months or older but younger than 5 years old.**

¿Adivine quién necesita vacunarse contra la influenza? Su hijo. Las vacunas contra la influenza son recomendadas para niños a partir de los 6 meses y hasta los 5 años de edad.



If your child is 6 months or older but younger than 5 years old, call your doctor's office to schedule flu shots.

Si su hijo tiene 6 meses o más pero es menor de 5 años de edad, llame a su consultorio médico para hacer una cita para que le apliquen las vacunas contra la influenza.

Guess who needs a flu shot?!



If your child is **6 months or older but younger than 5 years old**, ask your child's doctor about a flu shot.

Your child.

¿Adivine quién necesita vacunarse contra la influenza? Su hijo. Si su hijo tiene 6 meses o más pero es menor de 5 años de edad, consulte con su pediatra sobre la vacuna contra la influenza.