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## FDA NEWS

### FDA Grants First Full Approval to Pfizer COVID Vaccine

On August 23, 2021, the U.S. Food and Drug Administration announced full approval of the Pfizer COVID vaccine, the first such vaccine to reach this milestone. The Pfizer vaccine has been approved for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under Emergency Use Authorization for individuals 12 through 15 years of age. The agency also previously approved an additional (third) dose of the vaccine in certain immunocompromised individuals, specifically, organ transplant recipients and those diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Pfizer has named their COVID vaccine **Comirnaty** (pronounced Koe-mir'-na-tee). According to a company representative, the name "represents a combination of the terms COVID-19, mRNA, community, and immunity."

## .....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

### CDC Advice on Influenza Vaccination for 2021/2022 Season

The United States Centers for Disease Control and Prevention (CDC) has issued wide-ranging guidelines addressing the upcoming influenza vaccination season in the context of the continuing Coronavirus pandemic. The document, updated on August 27, 2021, includes advice for patients, as well as for healthcare professionals who will be administering the seasonal influenza vaccine. The major points, summarized and discussed in an FAQ format<sup>1</sup>, include:

- **Can COVID-19 vaccines and influenza vaccines be administered at the same time?** Current guidance for the administration of COVID-19 vaccines state that they may be administered with other vaccines, including flu vaccines. Providers should be aware, however, of the potential for increased reactogenicity with coadministration. If given together, COVID-19 and flu vaccines that might be more likely to cause a local reaction (for example, High Dose and adjuvanted [**Fluad**] influenza vaccines) should be administered in different limbs.
- **Can other routine vaccinations and influenza vaccines be administered at the same time?** Inactivated influenza vaccines may be administered concurrently or sequentially with other live or inactivated vaccines. Injectable vaccines given simultaneously should be administered at separate anatomic sites. Since the immunogenicity and safety of simultaneous or sequential administration of two vaccines containing non-aluminum adjuvants has not yet been evaluated, **Shingrix** should not be coadministered with **Fluad**. Patients requiring a shingles vaccine at the time of their flu vaccine should receive one of the many non-adjuvanted influenza vaccines available (**Afluria**, **Fluzone**, etc.).
- **When is the best time to get my influenza vaccine?** September and October are generally good times to be vaccinated. Ideally, everyone should be vaccinated by the end of October. Adults, especially those older than 65, **SHOULD NOT** get vaccinated early (in July or August) because protection in this group may decrease over time.
- **Which influenza vaccines are recommended for people aged 65 years and older?** Person aged ≥65 years may receive any age-appropriate inactivated influenza vaccine. However, data support greater benefit from three specific formulations: **Fluzone High Dose**, **Fluad**, and **Flublok**. Fluzone High Dose contains 4 times the amount of antigen as a standard dose vaccine. Fluad is a standard dose vaccine to which a non-aluminum adjuvant has been added to boost immune response. Both Fluzone High Dose and Fluad are indicated for use only in patients 65 years of age and older. Flublok is a recombinant influenza vaccine, which contains 3 times the amount of antigen as a standard dose vaccine, and is indicated for use in patients 18 years and older.
- **Should a flu vaccine be given to someone with suspected or confirmed COVID-19?** No. Flu vaccination should be deferred for people with suspected or confirmed COVID-19, whether or not they have symptoms, until they have met the criteria to discontinue their isolation. The current recommendations for the duration of isolation are as follows:
  - ◇ For most adults with COVID-19 illness, isolation and precautions can be discontinued 10 days *after symptom onset* and after resolution of fever for at least 24 hours, without use of fever-reducing medications, and with improvement of other symptoms. Some adults with severe illness may require extending duration of isolation for up to 20 days after symptom onset.
  - ◇ For adults who never develop symptoms, isolation and other precautions can be discontinued 10 days *after the date of their first positive RT-PCR test result for SARS-CoV-2 RNA*.



## Federal Regulator Expands Pharmacy Technician Vaccination Authorization

The Department of Health and Human Services has published an eighth amendment to the Public Readiness and Emergency Preparedness (PREP) Act. The update, issued on August 4, 2021, authorizes qualified pharmacy technicians to administer influenza vaccines to persons aged 19 or older. This adds to the previous PREP amendments which authorized qualified pharmacy technicians to administer COVID-19 vaccines and all ACIP recommended childhood vaccines (see chart below for specifics). The amendment to section V also clarifies the fact that pharmacy technicians are considered “qualified persons” covered by the Declaration, and reads as follows:

*Subsection V(d) authorizes:*

*A State-licensed pharmacist who orders and administers, and pharmacy interns and qualified pharmacy technicians who administer (if the intern or technician acts under the supervision of such pharmacist and the intern or technician is licensed or registered by his or her State board of pharmacy), (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages 3 to 18 according to ACIP’s standard immunization schedule or (2) seasonal influenza vaccines that ACIP recommends to persons aged 19 and older, or (3) FDA authorized COVID-19 vaccines to persons ages 3 or older.*

In order to qualify, pharmacy technicians must complete all applicable immunization training, including basic cardiopulmonary resuscitation, and be registered by their State pharmacy board. In addition, the supervising pharmacist must be readily and immediately available to the qualified pharmacy technician. This authorization preempts any state or local law that prohibits or effectively prohibits those who satisfy these requirements from administering these vaccines.

### **List of Vaccines Pharmacy Technicians are Authorized to Administer Under PREP**

- FDA authorized COVID-19 vaccines to persons ages 3 or older (current FDA authorization is limited to 12 years and older).
- All FDA authorized, ACIP recommended childhood vaccines to persons ages 3 to 18, according to ACIP’s standard immunization schedule.
- ACIP recommended seasonal influenza vaccines to persons aged 19 years and older.

## New York State Establishes the Profession of Registered Pharmacy Technician

Article 137-A of the New York State Education Law, which became effective on April 25, 2021, established the new profession of registered pharmacy technician. Since then, the state has licensed more than 2000 pharmacy technicians. To be licensed as a registered pharmacy technician, an applicant must meet the following requirements:

1. Be at least 18 years of age;
2. Hold a high school diploma, or its equivalent;
3. Have certification from a nationally accredited pharmacy technician certification program;
4. Be of good moral character as determined by the Department;
5. Submit a fee of \$75 for initial licensure and \$100 for initial registration to the Department; and
6. File an application with the department.

Article 137-A also increased the pharmacist/technician ratio: a pharmacist may now supervise up to a maximum of four individuals, in any pharmacy setting, at one time.

# Update on Vaccines for the 2021-22 Flu Season

**Our Second** post COVID-19 flu season is approaching, and in light of the ongoing Coronavirus pandemic, it is more important than ever to protect our patients from contracting influenza, the symptoms of which mimic COVID-19 in many respects. We are focusing this year's report specifically on prefilled quadrivalent vaccine products, since these are the doses most often administered by pharmacists in the community pharmacy setting.

## Quadrivalent Influenza Vaccine

The 2021-22 quadrivalent egg-based influenza vaccines contain the following 4 antigens:

- **A/Victoria/2570/2019 (H1N1) pdm09-like virus**
- **A/Cambodia/e0826360/2020 (H3N2)-like virus**
- **B/Washington/02/2019-like virus (B/Victoria lineage)**
- **B/Phuket/3073/2013-like virus (B/Yamagata lineage)**

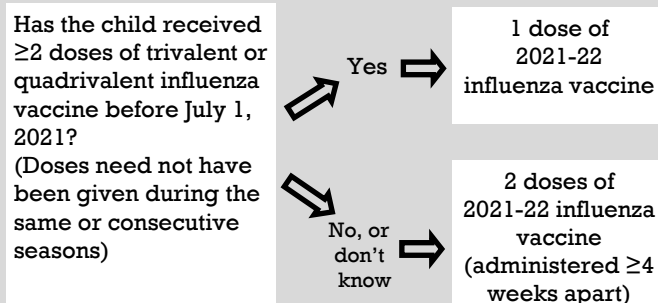
This year, *all* influenza vaccines will be quadrivalent. Licensure on one vaccine has changed: Flucelvax Quadrivalent is now approved for people 2 years of age and older (it was previously approved for 4 years and up). Guidance concerning two flu vaccines—Flucelvax and Flublok—was updated to include a precaution to their use in patients with a history of a severe allergic reaction (e.g., anaphylaxis) to any other influenza vaccine.

The 2020-21 quadrivalent cell- or recombinant-based—influenza vaccines (**Flucelvax** and **Flublok**) contain one slightly different “A” (H1N1) component:

- **A/Wisconsin/588/2019 (H1N1) pdm09-like virus**

## Special Considerations for Pediatric Patients

Legislation signed into law in 2018 authorizes pharmacists in New York State to administer influenza vaccine to patients 2 years of age and older (previously, pharmacists were limited to patients 18 years old and up). There are several clinical issues pharmacists must familiarize themselves with in regard to vaccinating this population. For example, children under the age of 9 *may* require 2 doses of the influenza vaccine, administered at least 4 weeks apart, depending on prior history. Here is an algorithm to determine if a child under age 9 will need 2 doses of vaccine<sup>1</sup>:



## Quadrivalent Influenza Vaccines (prefilled) for the 2021-2022 Season

Vaccine Trade Name (Manufacturer)	Presentation	Age Indication	Vaccine type
<b>AFLURIA</b> (Seqirus)	0.25 mL Prefilled Syringe 0.5 mL Prefilled Syringe	6 months to 35 months ≥ 3 years old	Inactivated quadrivalent egg-based (IIV4)
<b>FLUARIX</b> (GlaxoSmithKline)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
<b>FLULAVAL</b> (GlaxoSmithKline)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
<b>FLUZONE</b> (Sanofi Pasteur)	0.5 mL Prefilled Syringe	≥ 6 months old	Inactivated quadrivalent egg-based (IIV4)
<b>FLUCELVAX</b> (Seqirus)	0.5 mL Prefilled Syringe	≥ 2 years old	Inactivated quadrivalent cell-based (cIIV4)
<b>FLUBLOK</b> (Sanofi Pasteur)	0.5 mL Prefilled Syringe	≥ 18 years old	Recombinant influenza quadrivalent (RIV4)
<b>FLUZONE HIGH-DOSE</b> (Sanofi Pasteur)	0.7 mL Prefilled Syringe	≥ 65 years old	High Dose inactivated quadrivalent egg-based (HD-IIV4)
<b>FLUAD</b> (Seqirus)	0.5 mL Prefilled Syringe	≥ 65 years old	Adjuvanted quadrivalent egg-based (aIIV4)

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# ASK PRN...

**What is the latest guidance regarding influenza vaccination of people with a history of egg allergy?**

The latest CDC guidance states the following:

- Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive influenza vaccine. Any licensed, recommended influenza vaccine that is otherwise appropriate for the recipient's age and health status can be used.
- Persons who report having had reactions to egg involving symptoms other than urticaria (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent vomiting) or who required epinephrine or another emergency medical intervention can similarly receive any licensed, recommended influenza vaccine

that is otherwise appropriate for their age and health status. However, if a vaccine other than **Flucelvax** or **Flublok** is used, the selected vaccine should be administered in an inpatient or outpatient medical setting (including but not limited to hospitals, clinics, health departments, and physician's offices). Vaccine administration should be supervised by a health care provider who is able to recognize and manage severe allergic reactions. No postvaccination period is recommended specifically for egg-allergic persons. However, ACIP recommends that vaccine providers consider observing patients (seated or supine) for 15 minutes after administration of any vaccine to decrease the risk for injury should syncope occur.

## GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:  
[questions@prnnewsletter.com](mailto:questions@prnnewsletter.com)

*PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.*

## DID YOU KNOW?

**DID YOU KNOW** that the CDC once had a mascot, and it was, of all things, a bee? Introduced in 1962, "Wellbee" was described in a press release as a "pleasant-faced, bright-eyed, happy cartoon character, who is the personification of good health." The agency, which was then known as the Communicable Disease Center, used Wellbee on posters and pamphlets, on TV and radio, to promote a variety of campaigns encouraging healthy behaviors. Here we see Wellbee urging everyone to "Be Well! Take the oral polio vaccine! Tastes good!" Those of you of a certain age will remember that vaccine, which was administered in a sugar cube!



## PHARMACY FUN

It's time for our annual back-to-school quiz, and this year we present Pharmacology 101—answer all the following clues correctly and, using the first letter of each correct answer, spell the hidden word, which represents some people's favorite part of the school year! The first reader to submit the correct answers to us at [puzzle@prnnewsletter.com](mailto:puzzle@prnnewsletter.com) will win a \$25 gift card from Amazon, which will be sent electronically to the winner's Amazon account.

- |                                  |                                |
|----------------------------------|--------------------------------|
| 1. Oral direct vasodilator       | 5. Purple foxglove??           |
| 2. Original PPI                  | 6. First anti-herpes antiviral |
| 3. Anesthetic and antiarrhythmic | 7. Romantic alpha-2 blocker    |
| 4. Used to be called Vasodilan   | 8. First MAO Type B inhibitor  |

Answers to last month's **PHARMACY FUN**:

1. Efavirenz 2. Theophylline 3. Isoniazid 4. Lactulose 5. Erythromycin 6. Yohimbine 7. Dantrolene 8. Ursodiol

Hidden Word: YULETIDE

## References:

1. Adapted from CDC Morbidity and Mortality Weekly Report. August 27, 2021-22. Retrieved from [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)