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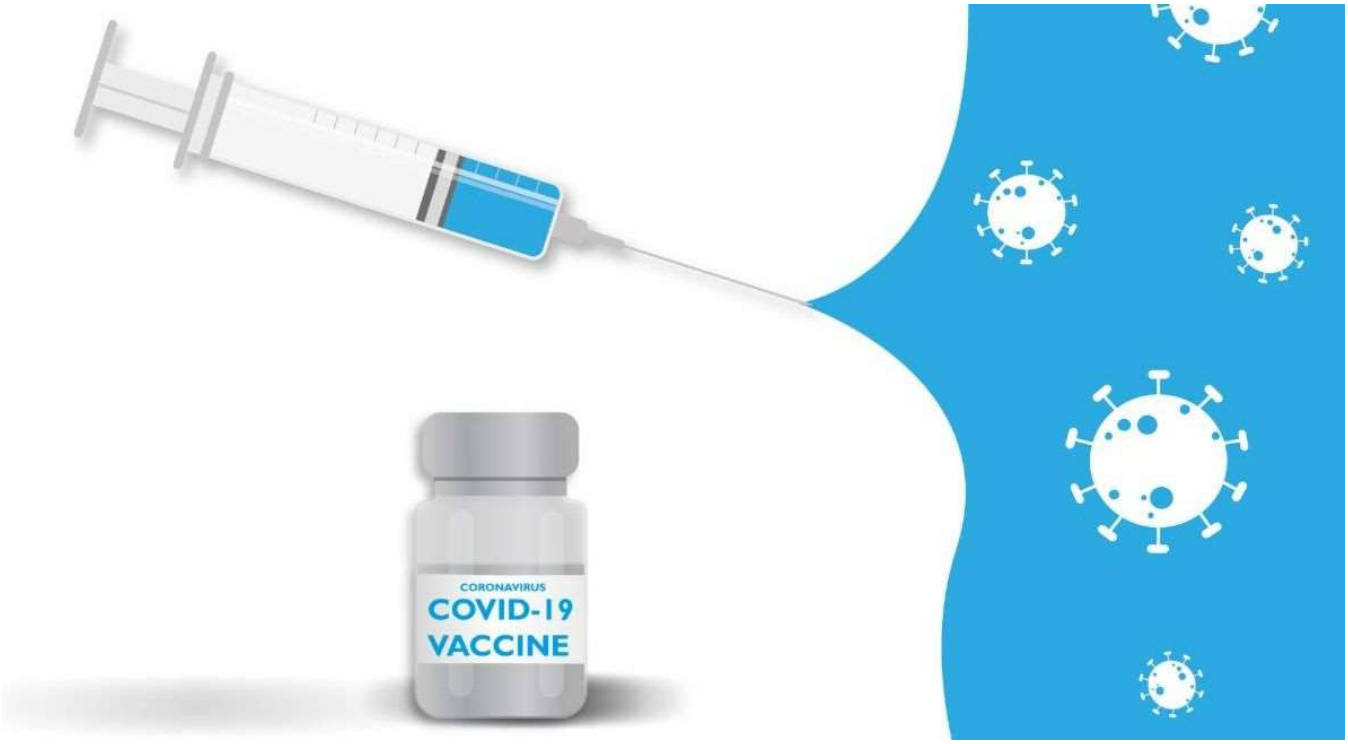
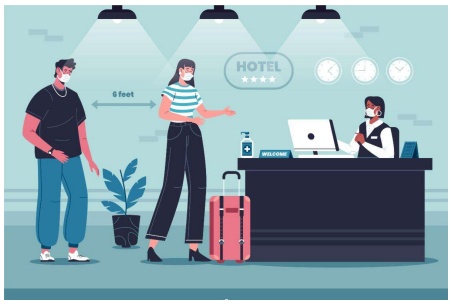
IMMUNIZATION COVID-19 Update

June 1, 2022| Issue 61



Question of the Week

What travel guidance is available to patients and/or the public?



The CDC recommends that individuals remain current with COVID-19 vaccines prior to travel. This includes **additional doses** for individuals who are immunocompromised or **booster doses** when eligible.

Additionally, travelers are advised to follow requirements and recommendations at each location during travel, and take steps to **protect themselves and others**.

Travelers can also review the **COVID-19 Travel Health Notice** for each destination and visit the **International Travel** webpage for requirements and recommendations.

Study examines post-COVID conditions in adults ages 18-65 and 65 and older

According to a study recently published in the CDC's *Morbidity and Mortality Weekly Report*, adults within certain age ranges are at a higher risk of experiencing long-term symptoms and potential organ dysfunction, also known as *long COVID*. More specifically, researchers found that COVID-19 survivors have twice the risk for developing pulmonary embolism or respiratory conditions. In addition, one in five COVID-19 survivors aged 18–64 years and one in four survivors aged 65 or older experienced at least one incident condition that might be attributable to previous COVID-19. **Read the study**.

Shelf-life extended for certain lots of Eli Lilly monoclonal antibodies

On May 20, FDA and the Department of Health & Human Services' Office of the Assistant Secretary for Preparedness and Response announced the **shelf-life extension for specific lots of the refrigerated Eli Lilly monoclonal antibody, bebtelovimab**, which is currently authorized for emergency use, has been extended from 12 months to 18 months.

FDA granted this extension following a thorough review of data submitted by Eli Lilly. As a result of this extension, some batches may be stored for an additional 6 months from the labeled date of expiry (see Table 1 **here**).

This extension applies to all unopened vials of bebtelovimab that have been held in accordance with storage conditions detailed in the authorized **Fact Sheet for Health Care Providers** (PDF, 433 KB) and the EUA **Letter of Authorization** (PDF, 111 KB) for bebtelovimab.

As required by the EUA, unopened vials of bebtelovimab injection, 175 mg/2 mL, must be stored under refrigerated temperature at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.

Evusheld's revised scope addresses hypersensitivity

On May 17, FDA **revised the scope of authorization** for Evusheld's emergency use authorization (EUA) to include new information on hypersensitivity reactions and the risk of cross-hypersensitivity with COVID-19 vaccines and related clinical recommendations. The FDA further recommends that clinicians consider consulting with an allergist/immunologist before administering Evusheld to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to a COVID-19 vaccine.

For all individuals, Evusheld should be administered under the supervision of a health care provider with appropriate medical support to manage severe allergic reactions. In addition, everyone who receives Evusheld should be observed after injection for at least one hour to monitor for hypersensitivity reactions.

Learn more about Evusheld's criteria for issuance of authorization, scope of authorization, limitations on authorized use, conditions of authorization.

Regulatory Education for Industry (REdI) Annual Conference

The Regulatory Education for Industry (REdI) Annual Conference 2022 will take place virtually on June 6-10. Dr. Robert M. Califf, Commissioner of Food and Drugs will serve as the keynote speaker for the event, which will reflect on

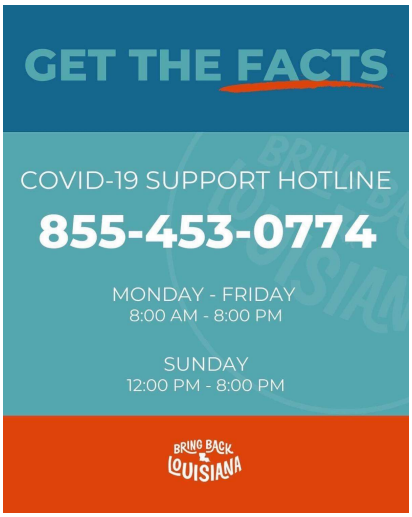
COVID-19 and FDA milestones, as well as explore the FDA's future approaches to addressing COVID-19.

Attendees will learn directly from the FDA's regulatory experts in medical product centers: drugs, devices and biologics. This course is designed to provide participants with a strong, basic foundation in the FDA's regulatory requirements.

Registration is free. To learn more, visit the **event page** to register, and view the **conference agenda**. This event will offer a total of 32.5 contact hours of continuing education for physicians, pharmacists, and nurses.

Good reads

- **COVID-19 vaccine immunity may be fading, doctors say; scientists work on new vaccine design**
- **NYT Opinion | PEPFAR Shows What a Global Response to Covid Can Look Like**
- **Reported COVID-19 infection levels nearly 6 times higher than last Memorial Day**
- **Louisiana suspends in-person visits at juvenile facilities due to confirmed COVID**



Submit a Question of the Week

Do you have a frequently asked question that you would like to submit or have answered in the QOW?

SUBMIT HERE