

## **COVID-19 Information**

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## **NEWS:** DailyMed Announcements

## **SEPTEMBER 13, 2021**

## Pfizer received FDA BLA license for its COVID-19 vaccine

Pfizer received FDA BLA license on 8/23/2021 for its COVID-19 vaccine for use in individuals 16 and older (<u>COMIRNATY</u>). At that time, the FDA published a BLA package insert that included the approved new COVID-19 vaccine tradename COMIRNATY and listed 2 new NDCs (0069-1000-03, 0069-1000-02) and images of labels with the new tradename.

At present, Pfizer does not plan to produce any product with these new NDCs and labels over the next few months while EUA authorized product is still available and being made available for U.S. distribution. As such, the CDC, AMA, and drug compendia may not publish these new codes until Pfizer has determined when the product will be produced with the BLA labels.

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