

Moderna readies for full vaccine approval, as Pfizer submits data on booster shot

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(HealthDay)—Moderna Inc. announced Wednesday that it has



completed its submission for full approval of its COVID-19 vaccine, while Pfizer Inc. said it has begun to file data for full approval of a third booster shot of its vaccine.

"This BLA [biologics license application] submission for our COVID-19 vaccine, which we began in June, is an important milestone in our battle against COVID-19 and for Moderna, as this is the first BLA submission in our company's history," Moderna CEO Stéphane Bancel said in a statement. "We are pleased that our COVID-19 vaccine is showing durable efficacy of 93 percent through six months after dose 2."

Right now, the Moderna vaccine is only authorized for emergency use in Americans 18 years and older. The company has also asked the U.S. Food and Drug Administration for an emergency use authorization for its vaccine in people aged 12 years and older, *CNN* reported. The Moderna COVID-19 vaccine would be the second to be fully approved by the FDA.

As for its booster shot, Pfizer said Wednesday it plans to complete the submission of a supplemental BLA for a third dose of its vaccine by the end of this week. A third dose of the vaccine is now available in the United States to people aged 12 years and older who are immunocompromised.

In a <u>statement</u>, the company described a trial of 306 people who got a booster between nearly five and eight months after getting the second dose. The trial revealed that the <u>vaccine</u> generated much higher levels of antibodies and was safe, with "mild-to-moderate" side effects, most commonly including injection site pain, fatigue, headache, muscle and joint pain, and chills.

More information: CNN Article



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