theepochtimes.com

Moderna Seeks FDA Authorization of Updated Covid Vaccine Ahead of Fall

Katabella Roberts

5–6 minutes

Pharmaceutical and biotechnology company Moderna has submitted an application to the U.S. Food and Drug Administration (FDA) for approval of its updated COVID vaccine ahead of the fall, the company announced on June 22.

The company's latest vaccine—the second update to its original shot—targets the XBB.1.5 subvariant of the virus in line with FDA guidance issued last week advising manufacturers updating their shots to target the subvariant, which became dominant in the United States earlier this year, according to estimates from the U.S. Centers for Disease Control and Prevention (CDC).

Rivals Pfizer and Novavax already began updating their vaccines targeting the variant and other subvariants currently circulating prior to the FDA issuing its guidance.

Moderna said that preliminary clinical data on the latest version of its XBB.1.5 monovalent vaccine demonstrated a "robust immune response" against multiple XBB descendent sublineages, such as XBB.1.5, XBB.1.16, and XBB.2.3.2.

Unlike Moerna's bivalent vaccine which was made available last

year, the updated shot does not contain a component of the Wuhan variant, which experts have said is due to signs of immune imprinting, which could make them less effective.

Side effects of Moderna's newly updated vaccine include pain at the injection site, headache, fatigue, myalgia (muscle pain and aches), and chills.

Among those aged six months to 36 months of age, side effects also included pain and swelling, axillary (or groin) swelling and tenderness, fever, irritability and crying, loss of appetite, and sleepiness.

Reported Side Effects

In those aged 37 months of age and older who received the vaccine, nausea, vomiting, and a rash were also seen, the company said.

The FDA will now review Moderna's available efficacy and safety data on the updated vaccine, and, pending authorization, they will be available in time for the fall vaccination season, Moderna said.

"The agility of our mRNA platform has enabled us to update Spikevax, Moderna's COVID-19 vaccine, to target XBB variants with speed and clinical rigor," said Moderna CEO Stéphane Bancel in a statement.

"We have been working diligently for months to build ample supply, with doses ready to ship in time for the fall vaccination season in the Northern Hemisphere. In addition, our preliminary clinical testing has demonstrated that mRNA-1273.815 is effective in generating an immune response against the current XBB variants of concern," Bancel continued.

"Over the past three years, Spikevax has consistently reduced hospitalizations and severe disease outcomes from COVID-19, and we encourage individuals to speak to their healthcare providers about receiving an updated vaccine."

Moderna's latest application comes ahead of a fall vaccination campaign, despite the fact that there is no clear seasonality with COVID-19 like there is with viruses such as influenza.

Vaccine Data

According to the latest CDC data, 81.4 percent of the U.S. population has received one dose of a COVID-19 vaccine to date, while less than 70 percent have completed a "primary series," and just 17 percent have received an updated bivalent shot, which experts said provided protection against the ancestral strain as well as the BA.4 and BA.5 omicron subvariants.

However, various research, including the CDC's own data, has shown that the bivalent vaccines from Pfizer/BioNTech or Moderna barely protect against severe illness, and protection generally drops off after a few months.

That data showed that protection against severe illness for adults from either of the company's bivalent vaccines began above 50 percent—which U.S. officials and World Health Organization experts say is the threshold for a successful vaccine—but quickly waned within months

In individuals aged 18–65 who were not immuno-compromised, a dose of the vaccine increased protection against hospitalization from 21 percent to 68 percent, but the protection quickly declined to 27 percent between 60–119 days later.

For those aged 65 and older, protection from the bivalent vaccine dose against hospitalization increased from 25 percent to 64 percent, but fell to 39 percent 120–179 days later.

The FDA is currently working on making public data it relied on to license COVID-19 vaccines by the middle of 2025 as part of a lawsuit filed by parents of children who were injured after receiving the shots.

Mimi Nguyen Ly and Reuters contributed to this report.