Written by **Veronika Kyrylenko** on August 31, 2026

FDA Approves New Covid Shots From Pfizer and Moderna

The Food and Drug Administration (FDA) approved Pfizer and Moderna's updated mRNA Covid vaccines last Thursday. The shots target the XFG variant selected for the 2026-2027 season. The strain-specific evidence publicly presented to regulators came from small mouse studies; at the time of approval, prospective human safety and immunogenicity studies of the updated formulations had not yet begun.

The approvals cover a large population. Pfizer's Comirnaty XFG is approved for everyone 65 and older and for people ages 5 through 64 with at least one condition that puts them at "high risk" for severe Covid.

Moderna has two updated shots. Spikevax is approved for everyone 65 and older and for patients as young as 6 months who have an underlying condition associated with severe Covid. mNEXSPIKE is approved for everyone 65 and older and for people ages 12 through 64 who meet the same risk-based criteria.

This marks the second annual round of updated Covid vaccine approvals under Health and Human Services (HHS) Secretary Robert F. Kennedy Jr., who once called the Covid vaccines tools of "mass murder."

President Donald Trump's administration had lined up substantial purchasing capacity before FDA approved the new formulas. In June, the Centers for Disease Control and Prevention (CDC) awarded Pfizer and Moderna four contracts worth up to $1.55 billion for Covid vaccines for this season.

Supplemental BLAs

Both companies received supplemental Biologics License Application approvals, or sBLAs. An sBLA allows a manufacturer to change an already licensed biological product, including its formulation, labeling, or manufacturing, without seeking licensure for an entirely new product.

Here, FDA approved the XFG formulations as "modifications" of vaccines already on the market, rather than requiring Pfizer and Moderna to establish the safety and effectiveness of the updated shots from scratch.

Pfizer and Moderna

Pfizer and Moderna followed essentially the same regulatory path. Both relied on human data from earlier Covid vaccine formulations and nonclinical data for the new XFG versions.

Pfizer and BioNTech said FDA based its approval on a "cumulative body of evidence." That included "clinical, non-clinical and real-world data" previously generated for Comirnaty, along with manufacturing and "quality" information. But for the XFG formulation itself, Pfizer cited "nonclinical

data," not results from people who had received the 2026-2027 shot.

Moderna likewise presented human data from previous formulations and animal "immunogenicity" data on the updated candidates.

Put simply, the human evidence came from earlier versions of the vaccines, which HHS continues to describe as "safe and effective" despite mounting evidence of harm. The XFG-specific evidence came from animals.

At the same time, immunogenicity is not a direct measure of clinical protection. It shows that a vaccine triggers an immune response, such as neutralizing antibodies. By itself, it does not establish how well the shot prevents infection, hospitalization, or death. Nor does it establish safety.

Both companies said the updated shots would become available within "days" of approval.

The prescribing information also retains warnings for myocarditis and pericarditis following mRNA Covid vaccination. Moderna says the conditions have occurred most frequently in males ages 12 through 24, and Pfizer's Comirnaty labeling carries the same warning.

Last December, then-FDA Commissioner Marty Makary also refused to add a "black box" warning to Covid vaccines, even after the agency's own safety officials recommended one over myocarditis concerns.

Mice Studies

In his Substack essay on the approvals, Nicolas Hulscher of the McCullough Foundation underscores how little XFG-specific evidence FDA had before approval, pointing to the agency's own materials. Pfizer's key study used 10 mice per group. Moderna's used eight. Both reported stronger "neutralizing responses" against XFG or related JN.1 variants.

Writes Hulscher:

> Pfizer's new COMIRNATY formulation was approved on **August 27, 2026**, while its prospective human study of the 2026-2027 formula is scheduled to begin **August 31, four days later**.
>
> Moderna's new SPIKEVAX formulation was also approved on **August 27**, but its Phase 3b/4 human study of the 2026-2027 SPIKEVAX and MNEXSPIKE formulations is not scheduled to begin until **November 16, nearly three months after approval**. [Emphasis in original.]

As a result, recipients of the updated boosters will effectively serve as human guinea pigs, since FDA has no direct human safety or effectiveness data on these new formulations.

Placebo Studies Dropped

The August 27 approval letters contain another notable change.

FDA released Pfizer from a placebo-controlled postmarketing study required in 2025. It would have measured circulating SARS-CoV-2 spike antigen and tracked symptoms at one, three, six, and 12 months in vaccinated and control groups. FDA said "operational and feasibility challenges" prevented the study from proceeding as designed.

The agency replaced it with new "commitments." One will examine where vaccine-derived spike protein

travels in the body and how long it persists after Comirnaty administration. Another will retrospectively search Pfizer trial data for symptom clusters described in the literature on post-Covid vaccination syndrome.

FDA also released Moderna from a randomized, observer-blind, placebo-controlled safety study of variant-containing mRNA vaccines in adults ages 50 through 64 without "high-risk" conditions, again citing "operational and feasibility challenges." FDA replaced the study with nonclinical work on biodistribution and spike persistence, plus a retrospective analysis of existing trial data. The changes appear in the approval letters for mNEXSPIKE and Spikevax.

The regulatory contradiction is staggering. After years of widespread use, FDA is now asking where vaccine-derived spike protein goes, how long it remains in the body, and whether the companies' own trial participants showed symptom patterns associated with post-Covid vaccination syndrome. Yet the agency has simultaneously dropped placebo-controlled studies that could have directly compared vaccinated and unvaccinated groups.

The decisions follow a new Covid vaccine framework announced in 2025 by former top FDA officials Makary and Vinay Prasad. They said the agency would require randomized trial evidence for repeat vaccination in healthy people under 65, while continuing to make the shots available to older and "high-risk" people based largely on immunogenicity. Strikingly, they framed this approach as "a balance of regulatory flexibility and a commitment to gold-standard science."

PREP Act Protection Remains

One major pandemic-era protection also remains.

Kennedy announced in June that HHS would terminate the Covid emergency use authorization declarations (EUAs) for drugs, biologics, and medical devices after transition periods. But that action did not terminate the separate Covid declaration under the Public Readiness and Emergency Preparedness (PREP) Act.

Former HHS Secretary Xavier Becerra extended that declaration through December 31, 2029. It covers FDA-licensed Covid vaccines, including Pfizer and Moderna products, and provides broad liability immunity to covered manufacturers, distributors, program planners, and qualified persons. The principal statutory exception is willful misconduct, which in practice is nearly impossible to prove.