

FDA approves omicron-specific booster shots from Pfizer, Moderna

31 August 2022



The U.S. Food and Drug Administration on Wednesday gave the green light to updated COVID-19 booster shots from both Pfizer and Moderna that target omicron variants, paving the way for the shots to get into American arms within a few days.

"The FDA has been planning for the possibility that the composition of the COVID-19 vaccines would need to be modified to address circulating variants," Peter Marks, M.D., director of the FDA Center for Biologics Evaluation and Research, said in an agency news release announcing the emergency approval. "We sought input from our outside experts on the inclusion of an omicron component in COVID-19 boosters to provide better protection against COVID-19. We have worked closely with the vaccine manufacturers to ensure the development of these updated boosters was done safely and efficiently. The FDA has extensive experience with strain changes for annual influenza vaccines. We are confident in the evidence supporting these authorizations."

FDA Commissioner Robert Califf, M.D., urged Americans to get the new boosters. "As we head into fall and begin to spend more time indoors, we strongly encourage anyone who is eligible to consider receiving a <u>booster</u> dose with a bivalent [targets both the original virus and the omicron variants] COVID-19 vaccine to provide better protection against currently circulating variants," he said in the news release.

Now that the FDA has given its blessing, a <u>vaccine</u> advisory panel for the U.S. Centers for Disease Control and Prevention is set to <u>meet</u> Thursday and Friday to discuss who should get the updated boosters. Once the panel makes its recommendation, CDC Director Rochelle Walensky, M.D., is expected to sign off on those recommendations. The approvals will come before the possible emergence of a winter surge in COVID-19 cases.

The updated Moderna booster was authorized for those aged 18 years and older, while the Pfizer booster was approved for those 12 years and older, the FDA said. It should be given at least two months after primary vaccination or the original boosters.

More information: FDA Announcement

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