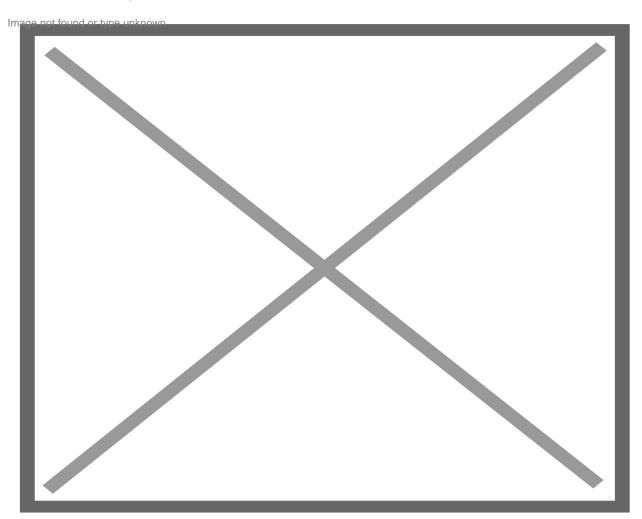
Dept. of Health Offering 'Bivalent' Covid-19 Vaccines Said to be More Effective Against Variants; Annual Shots Likely Path Forward

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The new bivalent Covid-19 vaccines from companies Moderna and Pfizer deemed more effective against variants are now available for use in the U.S. Virgin Islands, according to the V.I. Dept. of Health.

"The new formulation of the Covid-19 vaccine, the bivalent vaccine, which is more effective against the newest variants is now available at DOH clinics. We currently have 800 doses available in the territory (600 Pfizer and 200 Moderna)," stated Territorial Epidemiologist Dr. Esther Ellis, speaking during the Bryan administration's weekly press briefing on Tuesday. "Private providers are requesting their inventory as well. Anyone 12 and up for the Pfizer and 18 and up for Moderna qualifies to receive this new formulation if it has been at least two months

since your primary vaccine series. Alternatively, if you currently qualify for a booster, you can receive this bivalent vaccine as that booster."

Federal health authorities have said they expect booster Covid-19 shots to be taken annually based on current trends. "It is becoming increasingly clear that looking forward with the Covid-19 pandemic, in the absence of a dramatically different variant, we are likely moving towards a path with a vaccination cadence similar to that of the annual influenza vaccine, with annual updated Covid-19 shots matched to the currently circulating strains for most of the population," said Dr. Anthony Fauci, President Biden's chief medical adviser and the government's top infectious-disease official. "However, some particularly vulnerable groups may continue to need more frequent vaccination against Covid-19."

The Food and Drug Administration, which on Tuesday authorized emergency use of the new bivalent vaccines, described them as "updated boosters" that contain two messenger RNA (mRNA) components of SARS-CoV-2 virus, one of the original strain of SARS-CoV-2 and the other one in common between the BA.4 and BA.5 lineages of the omicron variant of SARS-CoV-2.

"The Moderna Covid-19 vaccine, bivalent, is authorized for use as a single booster dose in individuals 18 years of age and older. The Pfizer-BioNTech Covid-19 Vaccine, Bivalent, is authorized for use as a single booster dose in individuals 12 years of age and older," the FDA in a release announcing its decision to authorize emergency use of the shots.

"The COVID-19 vaccines, including boosters, continue to save countless lives and prevent the most serious outcomes (hospitalization and death) of COVID-19," said FDA Commissioner Robert M. Califf, M.D. "As we head into fall and begin to spend more time indoors, we strongly encourage anyone who is eligible to consider receiving a booster dose with a bivalent COVID-19 vaccine to provide better protection against currently circulating variants."

According to the FDA, here's what you need to know about the shots:

- The authorized bivalent COVID-19 vaccines, or updated boosters, include an mRNA component of the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component in common between the omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the omicron variant.
- The BA.4 and BA.5 lineages of the omicron variant are currently causing most cases of COVID-19 in the U.S. and are predicted to circulate this fall and winter. In June, the agency's Vaccines and Related Biological Products Advisory Committee voted overwhelmingly to include an omicron component in COVID-19 booster vaccines.
- For each bivalent COVID-19 vaccine, the FDA based its decision on the totality of available evidence, including extensive safety and effectiveness data for each of the monovalent mRNA COVID-19 vaccines, safety and immunogenicity data obtained from a clinical study of a bivalent COVID-19 vaccine that contained mRNA from omicron variant BA.1 lineage that is similar to each of the vaccines being authorized, and nonclinical data obtained using a bivalent COVID-19 vaccine that contained mRNA of the original strain and mRNA in common between the BA.4 and BA.5 lineages of the omicron variant.
- Based on the data supporting each of these authorizations, the bivalent COVID-19 vaccines are expected to provide increased protection against the currently circulating omicron variant. Individuals who receive a bivalent COVID-19 vaccine may experience side effects commonly reported by individuals who receive authorized or approved monovalent mRNA

COVID-19 vaccines.

- With today's authorization, the monovalent mRNA COVID-19 vaccines are not authorized as booster doses for individuals 12 years of age and older.
- The agency will work quickly to evaluate future data and submissions to support authorization of bivalent COVID-19 boosters for additional age groups as we receive them.

The V.I. Dept. of Health said that <u>as of Tuesday</u> there were 116 active Covid-19 cases on St. Croix, 86 on St. Croix and 1 on St. John for a total of 203. The territory's seven-day positivity rate stood at 10.53 percent.

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