US FDA approves freeze-dried version of Bavarian Nordic's mpox, smallpox vaccine

The company said the newly approved formulation of its vaccine, Jynneos, provides advantages in terms of transportation, storage conditions and shelf life, which are important factors for long-term stockpiling.

Bengaluru: Denmark's Bavarian Nordic said on Monday the U.S. Food and Drug Administration has approved a freeze-dried formulation of its mpox and smallpox vaccine.

The company said the newly approved formulation of its vaccine, Jynneos, provides advantages in terms of transportation, storage conditions and shelf life, which are important factors for long-term stockpiling.

The vaccine's liquid-frozen formulation, which was approved by the FDA in September 2019, had specific cold-chain requirements, Bavarian Nordic said.

The approval was primarily based on clinical data that showed comparability in terms of the immune responses and safety between the freeze-dried and liquid-frozen formulations, the company said.

Freeze-drying is a method used to remove water from a product, to extend its shelf life and stability.

Bavarian Nordic said it was contracted by the U.S Biomedical Advanced Research and Development Authority to develop and supply the freeze-dried version of Jynneos for stockpiling.

Manufacturing under this contract was initiated in 2024, and the first vaccines will be delivered later in 2025, it added.

In February, the World Health Organization said the mpox outbreak is still a public health emergency. Globally, there have been more than 25,000 cases confirmed by laboratory testing since the beginning of 2024, and over 70 deaths, mainly in Congo, according to the WHO.

As per the WHO, the United States is one of 18 countries with the new form of mpox, clade Ib, with 4 cases since the start of 2024, as of March 21.

News Source:

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