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Feb 1, 2002 (CIDRAP News) BioPort Corp of Lansing, Mich., yesterday received Food and Drug Administration (FDA) approval to begin routine distribution of its anthrax vaccine after more than 3 years of effort to bring its operation up to federal standards.

"FDA is now satisfied that BioPort's renovated facility can produce a vaccine that meets FDA standards for safety and efficacy," the agency said in a news release.

The FDA said it completed the clearance process yesterday by approving Hollister-Stier Laboratories, Spokane, Wash., as BioPort's contractor to fill vials with the anthrax vaccine. The agency had inspected Hollister-Stier's plant Jan 7 through 10, and had inspected and approved BioPort's manufacturing plant in December 2001.

BioPort, the only US producer of anthrax vaccine, makes the vaccine for the Department of Defense (DoD). The company was formed in 1998 to buy the manufacturing plant from the state of Michigan. The firm completed a plant renovation after the purchase and has been working since then to gain FDA approval of the operation; the vaccine itself was licensed by the FDA in 1970.

The FDA also announced it has released three lots of vaccine that were submitted for inspection in support of the license supplements for the plant renovation and Hollister-Stier's filling operation. Each lot of anthrax vaccine is tested for purity, potency, identity, and sterility by the FDA's Center for Biologics Evaluation and Research, the FDA noted.

All vaccine produced at the plant is owned by the Defense Department, company officials noted. More than half a million US troops have received the vaccine since a program to vaccinate all military personnel began in 1998. Because of a shortage of vaccine related to the delayed approval of BioPort's facility, the vaccination program was cut back in 2000 to focus only on troops considered to be at highest risk for anthrax exposure.

A DoD statement released yesterday said, "The department will continue to protect designated special mission units with the anthrax vaccine and is undertaking a thorough review of all factors to decides its future use of the vaccine. In doing so, the department's healthcare leaders have been consulting with the Department of Health and Human Services regarding possible civilian needs for the vaccine." Officials said they will make an announcement soon about the department's anthrax vaccination policy.

In December, the Department of Health and Human Services acquired thousands of doses of anthrax vaccine made in the renovated BioPort plant for possible civilian use. The vaccine was offered as an extra precaution to postal and government employees who had been exposed to anthrax in last fall's anthrax attacks, but few accepted the offer.

In welcoming the FDA's approval, BioPort President Robert Kramer commented in a press release, "Our 220 employees have kept their sense of dedication and focus for three years to get to this day. They've worked around the clock, and they've made countless personal sacrifices to gain this approval because they realize how vital the vaccine is to the protection of our military personnel."

See also:

Department of Defense statement on the BioPort licensure http://www.defenselink.mil/news/Jan2002/b01312002_bt047-01.html

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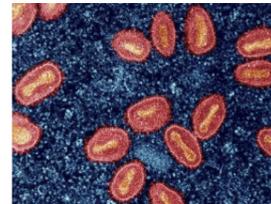
5 [Mpox cases spiking in 10 African nations](#)
 Some of the cases have been caused by what researchers are calling "clade 1b," a new mpox lineage identified in the DR Congo last year that is highly transmissible.
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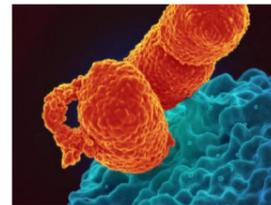
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 So far, humans who have been infected with H5N1 via contact with infected cows have also exhibited mild illness.
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7 [WHO considers public health emergency as mpox cases mount in Africa](#)
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 The WHO is particularly worried about ST23, an hvKp strain that carries carbapenem-resistance genes and has been detected in 12 countries.
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9 [CDC urges livestock workers get seasonal flu vaccine to cut pandemic risk](#)
 The CDC is offering support for targeted programs and vaccine supplies to states, part of a plan to cut the risk of H5N1 reassortment with seasonal flu.
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