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Medical Countermeasures Initiative Update

December 19, 2019



## First FDA-approved vaccine for the prevention of Ebola virus disease

## Approval marks a critical milestone in public health preparedness and response

The U.S. Food and Drug Administration announced today the approval of Ervebo, the first FDA-approved vaccine for the prevention of Ebola virus disease (EVD), caused by *Zaire ebolavirus* in individuals 18 years of age and older. Cases of EVD are very rare in the U.S., and those that have occurred have been the result of infections acquired by individuals in other countries who then traveled to the U.S., or health care workers who became ill after treating patients with EVD.

"While the risk of Ebola virus disease in the U.S. remains low, the U.S. government remains deeply committed to fighting devastating Ebola outbreaks in Africa, including the current outbreak in the Democratic Republic of the Congo," said Anna Abram, FDA Deputy Commissioner for Policy, Legislation, and International Affairs. "Today's approval is an important step in our continuing efforts to fight Ebola in close coordination with our partners across the U.S. Department of Health and Human Services, as well as our international partners, such as the World Health Organization. These efforts, including today's landmark approval, reflect the FDA's unwavering dedication to leveraging our expertise to facilitate the development

and availability of safe and effective medical products to address urgent public health needs and fight infectious diseases, as part of our vital public health mission."

More: read the full news release

## Related links:

- Ebola Preparedness and Response Updates from FDA
- Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review
- Tropical Disease Priority Review Voucher Program



This is a special news alert. Scheduled MCMi email updates will return in January 2020.

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