Emergency Use Authorization of Medical Products and Related Authorities

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats

January 2017

Procedural
OMB Control No. 0910-0595
Expiration Date 08/31/2022
See additional PRA statement in section IX of this guidance.

the quality and quantity of the available evidence, given the current state of scientific knowledge. The types of evidence that FDA may consider and that should be submitted to support a request for an EUA are discussed more fully in section III.D.2 of this guidance.

d. No Alternatives

For FDA to issue an EUA, there must be no adequate, approved, and available alternative to the candidate product for diagnosing, preventing, or treating the disease or condition. A potential alternative product may be considered "unavailable" if there are insufficient supplies of the approved alternative to fully meet the emergency need. A potential alternative product may be considered "inadequate" if, for example, there are contraindicating data for special circumstances or populations (e.g., children, immunocompromised individuals, or individuals with a drug allergy), if a dosage form of an approved product is inappropriate for use in a special population (e.g., a tablet for individuals who cannot swallow pills), or if the agent is or may be resistant to approved and available alternative products.