FDA issues final guidance on inhalational anthrax

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(HealthDay)—Final guidance has been issued by the U.S. Food and

Drug Administration to assist in the development of drugs for the prevention of inhalational anthrax for individuals who may have been exposed but who have not yet displayed related signs or symptoms.

The FDA's final guidance targets inhalational anthrax and revises the indication to "prophylaxis of inhalational anthrax" for the reduction of disease risk among those who have inhaled or are likely to inhale aerosolized *Bacillus anthracis* spores but who do not yet have established disease. The guidance is a result of efforts to advance the policy framework for development of treatments targeting inhalational anthrax.

Since naturally occurring inhalational anthrax is extremely rare and it would be unethical to expose human volunteers to *B. anthracis* spores, clinical trials cannot be conducted in humans. The final guidance clarifies that drugs developed for inhalational anthrax prophylaxis can rely on evidence from animal studies (the Animal Rule) to support approval when the criteria under the Animal Rule have been met.

"The FDA encourages drug developers to reference the final guidance issued today when designing studies to appropriately establish the safety and effectiveness of drugs for prophylaxis of inhalational anthrax," according to the agency's news brief.

More information: More Information