FDA NEWS RELEASE

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FDA approves first Botulism Antitoxin for use in neutralizing all seven known botulinum nerve toxin serotypes
Product to be stored in Strategic National Stockpile for emergency preparedness and responses

The U.S. Food and Drug Administration announced today that it has approved Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-(Equine) to treat patients showing signs of botulism following documented or suspected exposure to botulinum neurotoxin. The product is derived from horse plasma and contains a mixture of antibody fragments that neutralize all of the seven botulinum nerve toxin serotypes known to cause botulism.

Botulism is a rare but serious illness caused by ingesting or inhaling a botulinum nerve toxin, or by exposure arising from toxin secreted by Clostridium bacteria in a wound or the intestine. Patients with botulism develop severe muscle weakness that progresses from the head to the rest of the body. If untreated, the illness may progress to total loss of muscle function and inability to breathe. This heptavalent antitoxin is the only product available for the treatment of botulism in adults, and for cases of infant botulism caused by nerve toxins other than types A and B.

“This product approval meets an urgent unmet medical need for the treatment of sporadic cases of life-threatening botulism and provides a medical countermeasure should botulinum nerve toxins be used in a terrorism event,” said Karen Midthun, M.D., director of the FDA’s Center for Biologics Evaluation and Research.

The effectiveness of the product was studied in animals because it was not feasible or ethical to conduct efficacy studies in humans. These results provided substantial evidence that the antitoxin is reasonably likely to benefit humans with botulism. Under the FDA’s Animal Rule, the agency may approve a biological product when the results of well-controlled animal studies demonstrate that the product is reasonably likely to be effective, in addition to establishing safety in humans. This is the first approval of a plasma derivative using the Animal Rule.

The safety of the product was tested in 40 healthy human volunteers and also monitored in 228 patients who received the antitoxin experimentally under a botulism treatment program administered by the Centers for Disease Control and Prevention (CDC). The most commonly observed side effects were headache, fever, chills, rash, itching and nausea. Since the product is manufactured from horse plasma it may cause allergic reactions and a delayed hypersensitivity reaction (serum sickness) in people sensitive to horse proteins.

The product is manufactured by Cangene Corporation, based in Winnipeg, Canada. It was developed with support from the Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services’ Office of the Assistant Secretary for Preparedness and Response. The antitoxin will be maintained in the Strategic National Stockpile and distributed through the CDC’s Drug Service.

For more information:

- **FDA: Animal Rule Summary ()**
- **FDA: Medical Countermeasures Initiative (https://wayback.archive-it.org/7993/20170111193902/http://www.fda.gov/EmergencyPreparedness/MedicalCountermeasures/default.htm)**
- **CDC Emergency Preparedness & Response: Botulism (https://wayback.archive-it.org/7993/20170111193902/http://www.bt.cdc.gov/agent/botulism/)**
- **Biomedical Advanced Research and Development Authority (https://wayback.archive-it.org/7993/20170111193902/http://www.phe.gov/about/barda/Pages/default.aspx)**

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