

REGULATORY AFFAIRS: FAST TRACK VACCINE PROGRAMS

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In an on-demand, life-in-the-fast-lane world, the words "fast track" can mean many things. In the pharmaceutical industry, the U.S. Food and Drug Administration (FDA) grants Fast Track designation to certain products in order to expedite the development and review process. As a result, much-needed vaccines and treatments are sped through the licensure pipeline.

ABOUT FAST TRACK

The FDA's Fast Track Program is designed to facilitate the development and expedite the review of new drugs and biologics that 1) are intended to treat serious or life-threatening conditions and 2) demonstrate the potential to address unmet medical needs. According to a study conducted by the Tufts Center for the Study of Drug Development, clinical development time for fast track drugs approved between 1998 and 2003 was, on average two to two and a half years shorter than for non-fast track drugs. To be eligible for the Fast Track Program, an applicant must submit a request to the FDA with supporting documentation for the product. As of June 30, 2008, 64% of the Fast Track applications received by the FDA's Center for Biologics Evaluation and Research (CBER) have been granted Fast Track designation.

BIODEFENSE VACCINE PROGRAMS

Under the U.S. Department of Defense Joint Vaccine Acquisition Program (JVAP) prime systems contract, DVC is working to develop and license vaccines to counter the growing threat of biological warfare. To help protect warfighters, first responders and citizens, DVC has received Fast Track designation for three biological defense vaccine programs: Venezuelan equine encephalitis (VEE), botulinum neurotoxin (A/B) and plague. In addition to these programs, DVC received fast track designation for Vaccinia Immune Globulin (VIGIV), which became DVC's first FDA-licensed product in 2005.

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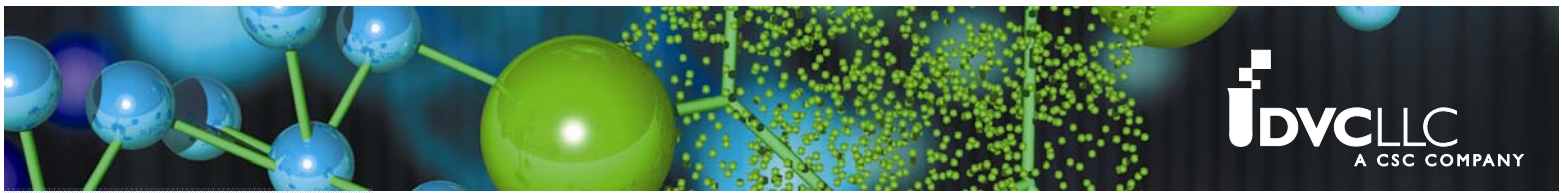
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Answers for Success





BOTULINUM NEUROTOXIN VACCINE PROGRAM

Botulinum neurotoxin is classified as a Category A bioterrorism agent by the U.S. Centers for Disease Control and Prevention (CDC) and poses a major threat because of its extreme potency and lethality. Phase 1 clinical testing of the vaccine candidate (rBot A/B) began in August 2004 and Phase 2 clinical testing is expected to start in 2008. Individual components of the bivalent vaccine were identified and developed by scientists at U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). Further development and manufacture of this vaccine candidate has been achieved by DVC, working as the prime systems contractor for JVAP.

PLAGUE VACCINE PROGRAM

Yersinia pestis infection causes plague disease, and is also classified as a Category A bioterrorism agent by the CDC. Currently, no licensed plague vaccine is available in the U.S. While streptomycin and tetracycline are approved by the FDA for treatment and prevention of plague, successful treatment is largely dependent on starting antibiotic therapy during the early stages of disease. DVC's plague vaccine candidate (rF1V) was originally identified and developed at USAMRIID. Following successful nonclinical efficacy and safety studies, DVC began the next step – human clinical trials of the vaccine. DVC initiated Phase 1 clinical trials in 2005 and is poised to complete the first of two Phase 2 clinical trials in 2008.

DELIVERING RESULTS ON THE FAST TRACK

“It shows great dedication to see the DoD, DVC and the FDA team up to get much-needed vaccines to approval. Early and frequent communication with the FDA is very important,” said Dr. Doris Snow, DVC Director of Regulatory Affairs. DVC's regulatory team has demonstrated its ability to work with scientific teams to develop efficient, responsive and effective FDA-licensure strategies, and produce quality investigational and marketing applications for our clients. Thanks to the skill and dedication of the DVC team, we are on the fast track to licensure for three crucial vaccines.

These products are currently under clinical investigation and have not been licensed by the FDA.



Sample vials and syringe.

