

## USAMMDA INFORMATION PAPER

**PRODUCT:** *CAMPYLOBACTER* VACCINE (NV/SW)

**DESCRIPTION:** The *Campylobacter* vaccine is an oral, monovalent, killed whole-cell *Campylobacter jejuni* (strain 81-176) vaccine, combined with a modified *E. coli* heat-labile toxin adjuvant, LT(R192G). The adjuvant is a recombinantly produced, genetically modified, less-toxic form of the *E. coli* heat-labile enterotoxin, that enhances the ability of the vaccine to elicit an immune response at the mucosal surfaces of the intestinal tract. The vaccine has been developed through a Cooperative Research and Development Agreement with Antex Biologics, Inc. *Campylobacter* bacteria are a major cause of diarrheal illness in both the developed and developing world. The annual number of cases worldwide is estimated at 400 million; in the U.S., some 2.5 million cases occur annually. This disease causes as much as 14 percent of diarrheal illness worldwide, and *Campylobacter* enteritis is considered the severest form of traveler's diarrhea. *Campylobacter* bacteria cause diarrhea, abdominal cramps and pain (may mimic appendicitis), fever, nausea and vomiting. The diarrhea can be bloody (dysentery). The illness typically lasts from 2 to 10 days. Prolonged illness may occur in adults and relapses can happen. A typhoid fever-like syndrome or reactive arthritis may occur, and rarely, convulsions, Guillain-Barré syndrome (GBS) or meningitis. *Campylobacter* is consistently the most common cause of diarrhea among U.S. Forces participating in Operations Balance Torch and Cobra Gold in Southeast Asia.

**PROGRAM RELEVANCE to the ARMY:** This product supports both the core mission of the Army and the Army Transformation. Of the Army's core competencies, this product supports: "Shape the Security Environment," "Forcible Entry Operations," "Sustained Land Dominance" and "Support Civil Authorities" by protecting U.S. Forces against diarrheal illness caused by *Campylobacter* bacteria. The *Campylobacter* vaccine will enhance the sustainability of U.S. Forces in regions of the world where *Campylobacter* disease is endemic. In addition, this product supports Future Operational Capability MD97-007 (Preventive Medicine).

**ISSUES/ ACTIONS:**

- Various safety and immunogenicity protocols have been executed over several years. Most recently, a Phase 1 clinical trial; was completed assessing vaccine safety and efficacy in 25 adults. Twenty percent of the vaccinees experienced gastrointestinal side effects. Fecal IgA responses were observed in 62 percent of the vaccines with a 13-fold rise from baseline. However, the elevated titers did not extend beyond day 22.
- Advanced development of a *Campylobacter jejuni* vaccine fell below the funding threshold in the prioritization list of October 2003. Until priorities or funding levels change, advanced development of this vaccine is on hold.
- Funding from the corporate partner, BioPort Corporation, ceased in October 2003 when they revised their research investment priorities.
- A new Science and Technology Objective was approved for *Campylobacter* vaccine research for FY2004-2008, with significant investment to complete GMP manufacturing of a recombinant flagellin vaccine for clinical trials.

**BPL #:** 196**DA PROJECT/TASK:** Infectious Diseases

PE/PROJ 643807.849ND

**MAMP RANK:** 5/36**ARMY ORD:** *Campylobacter* Vaccine; 23 Mar 95**SCHEDULE:**

MS I 4QFY94

MS II 3QFY97

MS FRP

**For additional information contact:** Pharmaceutical System Division, DSN 343-2051, Comm. 301-619-2051