SECTION C DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. Background

C.1.1. There is an operational requirement to develop a safe and effective product which will protect US troops against exposure from virulent strains of Bacillus anthracis. There is no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent.

C.1.2. Bacillus anthracis is a Gram positive spore-forming bacterium which in order to be considered fully virulent must not only produce a polyglutamic acid capsule but also produce a tripartite exotoxin. The toxin consists of three distinct proteins; protective antigen, lethal factor and edema factor. None of the protein components alone is biologically active however, protective antigen in combination with edema factor or lethal factor produces localized edema or death respectively in experimental animals.

C.1.3. A licensed vaccine against anthrax, which appears to afford some protection from the disease, is currently available for human use. This vaccine consists of alum-precipitated supernatant material obtained from fermenter cultures of an avirulent strain of Bacillus anthracis. The vaccine is composed primarily of the protective antigen component but does contain trace amounts of the lethal factor and edema factor components. The vaccine is, however, highly reactogenic, requires multiple boosters to maintain immunity and may not be protective against all strains of the anthrax bacillus.

C.2. Objective

C.2.1. This solicitation is for the production of a 500 bottle lot of a lypholized live spore preparation of Bacillus anthracis with associated diluent. The spore preparations shall be free of those culture medium components which might elicit allergic or other undesirable local or systemic reactions. Spore suspension diluent shall be pyrogen-free, sterile distilled water and shall contain no adjuvant. The spore preparation shall not contain detectable viruses or contaminating bacteria other than spores of the Bacillus anthracis strain used to produce the spore suspension.

C.3. Approach

C.3.1. The Government's requirements will be conducted in one initial development stage and a second stage, validation of the Technical Data Package. Government reviews will be conducted at the conclusion of phases in Stage I to examine the results, review progress and decide whether to proceed to the next phase.