INFORMATION PAPER

Military Vaccine Agency
18 July 2008

SUBJECT: Smallpox Vaccine Risk Management Action Plan (RiskMap)

1. Purpose. To describe the five areas of the smallpox vaccine RiskMap

2. Facts.

a. ACAM2000™ is a live vaccinia virus recently licensed by the U.S. Food and Drug Administration (FDA) for protection against smallpox disease. The FDA has required the manufacturer of ACAM2000™ complete five specific post-licensure activities in order to ensure continued licensure of the vaccine.

b. The ASD(HA) asked DoD medical organizations to support and participate in activities related to the ACAM2000™ RiskMap post-marketing requirements in collaboration with the manufacturer. The key DoD organizations include the Military Vaccine (MILVAX) Agency, Naval Health Research Center (NHRC), and the Vaccine Healthcare Centers (VHC).

c. ACAM2000™ RiskMap Post-marketing Requirements.

(1) Phase IV Prospective Safety Study. The primary objective of the Phase IV safety study is to compare rates of myo/pericarditis observed in 15,000 military subjects who received ACAM2000™ vaccine to 5,000 subjects in a non-vaccinated control group.

(2) Enhanced Surveillance Program. The goal of the enhanced surveillance program is to ascertain at least 75% of symptomatic cases of myo/pericarditis after ACAM2000™ vaccination.

(3) Myo/pericarditis Natural History Registry. The VHC will administer the myo/pericarditis registry. All myo/pericarditis cases identified from routine and enhanced surveillance as well as the Phase IV safety study of ACAM2000™ will be enrolled in the registry for follow-up of at least 2-5 years.

(4) Protocol for Evaluating the RiskMap. The protocol will describe methods for the annual evaluation of the ACAM2000™ RiskMap.

(5) Screening Study. The screening study will examine how effectively DoD adheres to its own screening procedures to identify potential vaccinees that have risk factors for more serious adverse events after vaccination, and therefore should not be vaccinated.

d. Study protocols will be reviewed by the U.S. Army Medical Research and Materiel Command Office of Research Protections Office, Human Research Protection Office. Study researchers will conduct studies in full compliance with all human research subject protection rules and FDA regulations.

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