DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE

WASHINGTON DC

31 January 2008

MEMORANDUM FOR ALMAJCOM/SG

FROM: HQ USAF/SG3
110 Luke Avenue, Room 400
Bolling AFB DC 20032-7050

SUBJECT: Transition to ACAM2000 Smallpox Vaccine

In late January, DoD begins transition to the use of the ACAM2000 smallpox vaccine, licensed for use in September 2007. All Dryvax vials will expire on 29 February 2008 and logistics personnel will be required to destroy all unused vaccine.

The indications for smallpox vaccination remain the same. Clinical screening, safety profile and use of both vaccines is very similar. Important differences include the following:

a. ACAM2000 vaccination requires a 15-jab scarification technique for all uses, whether providing an initial vaccination or booster.

b. ACAM2000 must be diluted with just 0.3 ml of diluent; though the vial provided contains 0.6 ml.

c. ACAM2000 expires 30-days after reconstitution; therefore clinics must be diligent in utilization to minimize vaccine loss.

As part of the licensing approval, the FDA mandated that every individual receiving ACAM2000 be provided with the official medication guide developed by the manufacturer. Immunization clinics will receive medication guides with vaccine shipments, and local reproduction of the guide is authorized. The DoD smallpox trifold must also be provided to individuals, as it includes DoD specific information about the program.

Medical Group commanders will ensure personnel providing smallpox vaccinations, and care to recipients, review the attached document and MILVAX ACAM2000 website for additional information. Immunization clinic OICs will ensure all technician are fully versed in the use of ACAM2000 before vaccinating. My POC for this issue is Col Michael Snedecor, AFMOA/SG3PM, (202) 767-4260, DSN 297-4260, or Michael.Snedecor@Pentagon.af.mil.

THOMAS J. LOFTUS
Major General, USAF, MC, CFS
Assistant Surgeon General, Health Care Operations
Office of the Surgeon General

Attachment:
MILVAX ACAM2000 Transition Guide

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

Military Vaccine Agency 23 January 2008

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Implementation Instructions for Transition to ACAM2000™ in the Department of Defense Smallpox Vaccination Program

1. **References**:

a. Department of Defense Directive (DODD) 6205.02E, *Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries*, 19 September 2006.

b. Under Secretary of Defense for Personnel and Readiness, *Policy on Administration Issues Related to Smallpox Vaccination Program (SVP),* 13 December 2002. Available at: http://www.smallpox.mil/documents/240SPadminIssuespolicy.pdf

c. Assistant Secretary of Defense for Health Affairs, *Clinical Policy for the Smallpox Vaccination Program (SVP)*, 26 November 2002. Available at: http://www.smallpox.mil/documents/219SPclinicalpolicy.pdf

d. Department of Defense Joint Regulation (Army Regulation 40–562, BUMEDINST 6230.15A, AFJI 48–110, CG COMDTINST M6230.4F), *Immunizations and Chemoprophylaxis*, 29 September 2006.

e. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), *ACAM2000™ - Product Approval Information*, 4 September 2007. Available at: http://www.fda.gov/cber/approvltr/acam2000083107L.htm

f. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Package Insert, *ACAM2000™ (Smallpox (Vaccinia) Vaccine, Live),* Available at: http://www.fda.gov/Cber/label/acam2000LB.pdf

g. Acambis Inc., *Deployment Guidance for ACAM2000™ Smallpox (Vaccinia) Vaccine, Live,* dated 27 December 2007. Available at: http://www.smallpox.mil/documents/1109ACAM2000DeploymentGuidance.pdf

h. Department of Defense, *Communication Plan – ACAM2000™ Vaccine Transition*, 10 January 2008. Available from the Military Vaccine (MILVAX) Agency.

i. Department of Defense educational brochure, *What You Need To Know About Smallpox Vaccine*, dated 1 August 2007. Available at: http://www.smallpox.mil/documents/1070SVPTrifold.pdf.

2. **Purpose.** To provide instructions to Service representatives for the transition of Dryvax® smallpox vaccine to ACAM2000™ smallpox vaccine in the Department of Defense Smallpox Vaccination Program (SVP).

3. **Summary**. The Department of Defense (DoD) is transitioning from Wyeth's Dryvax® brand of smallpox vaccine to Acambis' ACAM2000™ brand of smallpox vaccine. The Food and Drug Administration (FDA) approved licensure of ACAM2000™ on 31 August 2007. Subsequently, Wyeth (the manufacture of Dryvax®) announced its plan to withdraw licensure of Dryvax® vaccine. This transition will not affect DoD smallpox vaccination policy.

4. **Timeline**: There are two important dates in the transition process.

a. 29 February 2008: This is the date that DoD clinics should quarantine all Dryvax® smallpox vaccine and continue their smallpox vaccination programs with ACAM2000™ vaccine.

b. 31 March 2008. This is the suspense date for all DoD Dryvax® smallpox vaccine to be destroyed. During the month of March, destruction paperwork must be forwarded to the United States Army Medical Materiel Agency's Distribution Operations Center (USAMMA-DOC). Instruction can be found at www.usamma.army.mil.

5. **Smallpox Vaccination Program (SVP) Policy:** The DoD policy for the Smallpox Vaccination Program (SVP) remains the same. This transition to a new vaccine does not change the population being vaccinated or the previous requirements of the SVP.

6. **Clinical Requirements:** ACAM2000™ is administered similar to the Dryvax® vaccine by percutaneous route (scarification) using a bifurcated needle. Like the Dryvax® vaccine, ACAM2000™ should not be injected by the intradermal, subcutaneous, intramuscular, or intravenous route. Enclosure 1 provides a chart comparing the two vaccines. The significant three changes are:

a. After proper screening, all personnel receiving ACAM2000™ (primary vaccinees and re-vaccinees) will receive **15 jabs** with a bifurcated needle. Personnel handling or administering ACAM2000™ should wear gloves and change then between every vaccine recipient.

b. The bottle of diluent supplied with the ACAM2000™ vaccine kit contains more liquid than is needed to reconstitut the vaccine. Clinic personnel must make sure to use the correct (0.3 mL) amount and prevent over pressurizing the vaccine vial with too much volume.

c. ACAM2000™ contains a small amount of neomycin and polymyxin B. Individuals allergic to these and other vaccine components may be at a higher risk for adverse events after vaccination.

7. **Vaccine Safety**: ACAM2000™ was evaluated against Dryvax® smallpox vaccine in six prelicensure clinical studies and found to have a comparable side-effect profile. The most common side-effects following vaccination with ACAM2000™ include itching, swollen lymph nodes, sore arm, fever, headache, body ache, mild rash and fatigue. There was no statistical difference in the incidence of serious adverse events (e.g. myo/pericarditis) between ACAM2000™ and Dryvax®. The prelicensure analysis of ACAM2000™ provided sufficient data for the FDA to approve it for active immunization against smallpox disease.

8. **Education Requirements:** Prior to vaccination with ACAM2000™, all vaccinees must receive a copy of the FDA approved Medication Guide and the DoD Smallpox Individual Information Trifold Brochure. These are shipped to clinics at no cost in the same quantity as ordered vaccine. Additionally, clinics may request additional copies through MILVAX by phone 877-GET-VACC or email Vaccines@amedd.army.mil. The products are also available on-line for downloading at www.vaccines.mil/ACAM2000 or www.smallpox.mil.

9. **Vaccine Ordering, Storage, and Handling Procedures.**

a. The ordering process will remain the same. Customers will order ACAM2000™ from the USAMMA-DOC.

b. There are important distinctions between Dryvax® and ACAM2000™ in the areas of storage, handling, and reconstitution.

1) All un-reconstituted ACAM2000™ will have an **18-month expiration date**. This date is set by when the vaccine is pulled from the national Strategic Stockpile, not by individual lot numbers.

2) Un-reconstituted ACAM2000™ vaccine will be distributed and stored at 2-8°C (36-46°F).

3) Un-reconstituted ACAM2000™ should not be exposed to room temperature conditions (23-27°C, 73-81°F) for more than **48 hours**.

4) The diluent for ACAM2000™ vaccine can be stored at room temperature (15-30°C, 59-86 °F)

5) After reconstitution ACAM2000™ may be exposed to room temperature (20-25°C, 68-77°F) for up to 8 hour (i.e. clinic shift), after which it must be discarded as biohazard waste.

6) Once reconstituted, ACAM2000™ should be discarded as biohazardous waste after **30 days.**

c. DoD uses the same FDA approved vaccine that is maintained in the Strategic National Stockpile, therefore all DoD stock will have "Strategic National Stockpile Use Only" printed on its label. This vaccine is approved for use in the DoD.

10. **Immunization Record Keeping Procedures.** There is no change to the immunization record keeping requirements. Every vaccination must be entered into a DoD-approved electronic immunization tracking system.

11. POC for this message is LTC Patrick Garman, COM: 703-681-5101 or DSN: 761-5101.

Randall G. Anderson
Colonel, US Army
Director, Military Vaccine Agency

Enclosure 1
DISTRIBUTION:

CBRN Defense Policy, FHP&R, OASD(HA), (ATTN: CAPT Hottenstein)
Army Immunization Policy POC (ATTN: COL Stanek)
Navy Immunization Policy POC (ATTN: CAPT Naito)
Air Force Immunization Policy POC (ATTN: Col Snedecor)
Marine Corps Immunization Policy POC (ATTN: CDR Feeks)
Coast Guard Immunization Policy POC (ATTN: CDR Schwartz)
Joint Staff Immunization Policy POC (ATTN: LTC Silver)
USAMMA Distribution Operations Center (ATTN: LTC Williams)

DRYVAX/ACAM2000

Comparison Chart

	DRYVAX® (est. thru 29 Feb 08)	ACAM2000™ (est. after 01 Mar 08)
Manufacturer	Wyeth Lab	Acambis Inc.
Indication	For the induction of immunity against Smallpox	For the induction of immunity against Smallpox
Description	Live vaccinia virus cultured from Calf Lymph	Live vaccinia virus manufactured using cell culture technology
Pharmaceutical Properties	~ The calf lymph is purified, concentrated and dried by lyophilization. During processing, polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride and neomycin sulfate are added. ~ Diluent contains: 50% glycerin and 0.25% phenol ~ 100 dose vial	~ 2% human serum albumin USP, 0.5-0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of neomycin and polymyxin B ~ Diluent for ACAM2000 contains 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP supplied in 3mL clear glass vials containing 0.6mL of diluent ~ 100 dose vial
Medium	Calf Lymph	Vero (African Green Monkey kidney cells)
Route	Precutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)	Precutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)
Dosing	Primary: 3 Jabs Revaccination:15 Jabs	Primary: 15 Jabs Revaccination:15 Jabs
Revaccination	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.
Storage & Handling	~ Dryvax is shipped and stored at 2-8°C or 36-46°F ~ Discard vaccine 90 days after reconstitution ~ Expiration date subject to extensions	~ Un-reconstituted ACAM2000 vaccine is shipped and stored at 2-8°C (36-46°F) ~ Un-reconstituted ACAM2000 vaccine should not be exposed to room temperature (23-27°C, 73-81°F) for more than 48 hours ~ After reconstitution, ACAM 2000 vaccine may be administered within 6 to 8 hours at room temperature (20-25°C, 68-77°F) ~ Vaccine must be discarded as a bio-hazardous material 30 days after reconstitution ~ Gloves should be worn when reconstituting or administering ACAM2000 vaccine ~ Expiration dates will not be extended
Required Educational Material	DoD Smallpox individual information trifold brochure	DoD Smallpox individual information trifold brochure AND *Medication Guide*

Military Vaccine Agency *www.vaccines.mil* *(877) GET-VACC* 10 Jan 08

Enclosure 1