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PRECEDENCE TO: ROUTINE DTG: 201300Z JAN 06  
PRECEDENCE CC: ROUTINE  
TYPE: DMS SIGNED/ENCRYPTED  
FROM PLA: HQ USAF WASHINGTON DC//XO//  
FROM D/N: C:US,O:U.S. Government,OU:DoD,OU:AF,OU:ORGANIZATIONS,  
L:PENTAGON WASHINGTON DC,OU:HQ USAF(uc),OU:XO(uc)  
SUBJECT: EXTENSION OF AUTHORIZATION FOR ANTHRAX VACCINATIONS  
TEXT:  
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FM HQ USAF WASHINGTON DC//XO//  
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HQ NGB WASHINGTON DC//CV//  
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INFO ALMAJCOM//DO/SG//  
HQ AFSPC PETERSON AFB CO//XO//  
HQ ANG ANDREWS AFB//SG//  
HQ ANG CRYSTAL CITY AFB//XO//  
HQ USAF WASHINGTON DC//DP/IL/JA/RE/SG/ILG/SGO/XOS/ILGC/SGOP/  
XOS-F/XOS-FC//  
SAF WASHINGTON DC//GC/MR/PA//  
7AF OSAN AB KOR//CC//  
9AF SHAW AFB SC//CC//  
AEFC LANGLEY AFB VA//CC//

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SUBJ: EXTENSION OF AUTHORIZATION FOR ANTHRAX VACCINATIONS

REF A. FDA DOCKET NO. 1980-0208, BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS; IMPLEMENTATION OF EFFICACY REVIEW; ANTHRAX VACCINE ADSORBED; FINAL ORDER. FEDERAL REGISTER 2005; VOLUME 70 (DEC 19)

REF B. DR WINKENWERDER MEMO, CONTINUATION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP), 22 DEC 05

REF C. AIR FORCE PLAN FOR IMPLEMENTING THE ANTHRAX VACCINE IMMUNIZATION PROGRAM (AVIP) UNDER EMERGENCY USE AUTHORIZATION (EUA) CONDITIONS, 26 JUL 05

REF D. HQ USAF/XO MESSAGE, EXTENSION OF EMERGENCY USE AUTHORIZATION FOR ANTHRAX VACCINATIONS, DTG 262050Z JUL 05

1. EFFECTIVE 15 DEC 05, OFFICIALS FROM THE FOOD AND DRUG ADMINISTRATION (FDA) ISSUED A FINAL ORDER (REF A), FINDING THAT ANTHRAX VACCINE ABSORBED (AVA) IS SAFE AND EFFECTIVE AGAINST ALL ROUTES OF EXPOSURE TO ANTHRAX SPORES, INCLUDING INHALATION. AFTER EVALUATION OF THE FULL SCIENTIFIC LITERATURE AND ASSESSING COMMENTS FROM THE PUBLIC SUBMITTED IN EARLY 2005, THE FDA FINALIZED ITS PROPOSED RULE LICENSING THE AVA.

2. BECAUSE THIS REGULATORY ACTION REMOVED THE BASIS AND NEED FOR THE EMERGENCY USE AUTHORIZATION (EUA) THAT DOD HAS FOLLOWED SINCE APR 05 (REF C), IT WILL NOT BE NECESSARY FOR DOD TO SEEK RENEWAL OF THE EUA FOR USE OF ANTHRAX VACCINE TO PREVENT INHALATION ANTHRAX. THE CURRENT EUA EXPIRES 14 JAN 06 (REF D).

3. WHILE OUR SENIOR CIVILIAN LEADERS COMPLETE A POLICY REVIEW, DOD WILL CONTINUE VOLUNTARY ANTHRAX VACCINATIONS IAW GUIDELINES FOR THE EUA (REF B). NO PERSONNEL OTHER THAN THOSE DESIGNATED AS ELIGIBLE UNDER THE EUA MAY RECEIVE VACCINATION. THIS INTERIM APPROACH WILL CONTINUE TO INCLUDE EDUCATIONAL BRIEFINGS, AN OPTION TO REFUSE, AND REPORTING REQUIREMENTS. COMPLETE REQUIREMENTS CAN BE FOUND IN REF C.

4. UNITS NOT CURRENTLY ADMINISTERING ANTHRAX VACCINATIONS UNDER AN APPROVED DESIGNATION LETTER FROM THE MILITARY VACCINE (MILVAX) AGENCY MUST REQUEST AUTHORIZATION IAW REF C BEFORE ANY VACCINATIONS CAN BE ADMINISTERED.

5. OICS OF ALL CERTIFIED IMMUNIZATION SITES WILL SUBMIT A FINAL WEEKLY REPORT DURING THE WEEK OF 16 JAN 06 DESCRIBING YOUR CLINIC OPERATIONS THROUGH THE END OF 14 JAN 06 (BECAUSE OF THE FEDERAL HOLIDAY, FILING ON TUESDAY IS ACCEPTABLE). IN THIS TRANSITIONAL REPORT, OICS WILL STATE THAT THEY HAVE READ THE 22 DEC 05 POLICY STATEMENT FROM THE ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS) AND WILL ABIDE BY IT ([www.anthrax.mil/documents/853continuation.pdf](http://www.anthrax.mil/documents/853continuation.pdf)).

6. FOLLOWING SUBMISSION OF THE FINAL WEEKLY REPORT, WEEKLY REPORTING REQUIREMENTS IN REF C ARE MODIFIED TO A MONTHLY REPORTING REQUIREMENT. IN THE FIRST SUCH REPORT, CLINIC OICS WILL DESCRIBE THE BALANCE OF JANUARY OPERATIONS (I.E., 15 JAN TO 31 JAN 06), DUE WITHIN THE FIRST 5 DAYS OF FEBRUARY. SUBSEQUENT REPORTS WILL BE BASED ON FULL CALENDAR MONTHS (E.G., 1-28 FEB 06, DUE WITHIN THE FIRST 5 DAYS OF MARCH). THE REPORT SHOULD DESCRIBE ANY NEWLY IDENTIFIED, UNREPORTED INVOLUNTARY VACCINATIONS, EVEN IF THE ACTUAL EVENT OCCURRED PRIOR TO THAT INTERVAL (BACK TO 27 OCT 04). REPORTS ARE TO BE SUBMITTED VIA FAX OR E-MAIL TO MILVAX IAW CONTACT INFORMATION IN REF C.

7. CLINICS OFFERING ANTRHAX VACCINATIONS WILL USE THE MOST CURRENT VERSION OF THE TRIFOLD BROCHURE FOR EDUCATION SESSIONS. BROCHURES WILL BE SHIPPED WITH VACCINE ORDERS AND CAN BE ORDERED BY EMAIL MESSAGE AT: [vaccines@amedd.army.mil](mailto:vaccines@amedd.army.mil). OLDER VERSIONS SHOULD BE DISCARDED TO PREVENT INADVERTENT USE.

8. A COMPLETE ARCHIVE OF AF GUIDANCE ON THE ANTHRAX VACCINATION PROGRAM, INCLUDING THIS MESSAGE AND ALL REFERENCES, IS AVAILABLE AT: [https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE\\_resource/biological/anthrax/index.asp](https://www.xo.hq.af.mil/xos/xosf/xosfc/CCBRNE_resource/biological/anthrax/index.asp)

9. HQ USAF POC FOR THIS MESSAGE IS LT COL DONNA HUDSON (AF/XOS-FC), 703-692-0371 (DSN 222), OR EMAIL: [DONNA.HUDSON@PENTAGON.AF.MIL](mailto:DONNA.HUDSON@PENTAGON.AF.MIL)

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