FM HQ USAF WASHINGTON DC//XO//

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HQ USAF WASHINGTON DC//JA/SG/SGO/XON/SGOP/XONP//

SAF//PA// 9AF//CC// AEFC

UNCLASSIFIED

REF A: DEPSECDEF MEMO, SUBJ: REINTRODUCTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM, 28 JUN 2002

REF B: USD/(P&R) MEMO, SUBJ: POLICY ON ADMINISTRATIVE ISSUES RELATED TO ANTHRAX VACCINE IMPLEMENTATION PROGRAM (AVIP), 6 AUG 02

REF C: CSAF MEMO, SUBJ: AIR FORCE ANTHRAX VACCINE IMPLEMENTATION PROGRAM, 11 OCT 02

REF D: USD(P&R) MEMO, SUBJ: ANTHRAX VACCINATION IMMUNIZATION PROGRAM, 23 DEC 03

REF E: HQ USAF/XO MSG, SUBJ: TEMPORARILY STOP GIVING ANTHRAX IMMUNIZATIONS TO ALL DOD PERSONNEL, DTG: 242037Z DEC 03

REF F: 21 CODE OF FEDERAL REGULATIONS, FDA FINAL RULE AND FINAL ORDER, SUBJ: BIOLOGICAL PRODUCTS; BACTERIAL VACCINES AND TOXOIDS;

IMPLEMENTATION OF EFFICACY REVIEW, 5 JAN 04,

http://www.fda.gov/OHRMS/DOCKETS/98fr/80n-0208-nfr0001.pdf

REF G: USD(P&R) MEMO, SUBJ: ANTHRAX VACCINE IMMUNIZATION PROGRAM RESUMPTION, 7 JAN 04

SUBJ: RESUMPTION OF ANTHRAX VACCINATIONS FOR DOD PERSONNEL

- 1. THIS MESSAGE AUTHORIZES AND DIRECTS IMMEDIATE RESUMPTION OF ANTHRAX VACCINATIONS IAW REF A, B, C, AND G.
- 2. REFS A, B, AND C PROVIDED AUTHORIZATION AND IMPLEMENTATION GUIDANCE FOR REINTRODUCTION OF THE ANTHRAX VACCINE IMMUNIZATION PROGRAM IN JUN 02 FOR DESIGNATED MILITARY, EMERGENCY-ESSENTIAL CIVILIANS AND MISSION-ESSENTIAL CONTRACTORS IAW THESE REFERENCES.
- 3. IN RESPONSE TO A 22 DEC 03 U.S. DISTRICT COURT RULING CONCERNING DOD'S ANTHRAX VACCINE IMMUNIZATION PROGRAM, DOD ISSUED A MEMORANDUM ON 23 DEC 03 DIRECTING A TEMPORARY STOP TO ALL ANTHRAX VACCINATIONS (REF D). SAFETY OF THE VACCINE WAS NOT THE FOCUS OF THE INJUNCTION. THE JUDGE'S RULING WAS BASED ON CONCERNS ABOUT THE

COMPLETENESS OF THE FOOD AND DRUG ADMINISTRATION'S (FDA) PROCESS TO APPROVE THE VACCINE FOR USE AGAINST INHALATION ANTHRAX.

- 4. REF E PROVIDED THE AIR FORCE DIRECTIVE TO TEMPORARILY STOP ALL ANTHRAX VACCINATIONS UNTIL FURTHER NOTICE.
- 5. ON 30 DEC 03, THE FDA COMPLETED AND APPROVED THE FINAL RULE THAT STATES ANTHRAX VACCINE ADSORBED (AVA, BIOTHRAX) IS SAFE AND EFFECTIVE AGAINST ALL FORMS OF ANTHRAX, INCLUDING INHALATIONAL ANTHRAX. THE FINAL RULE WAS PUBLISHED IN THE FEDERAL REGISTER ON 5 JAN 04 (REF F). ON 7 JAN 04, THE JUDGE GRANTED THE GOVERNMENT'S MOTION FOR A STAY OF HIS 22 DEC 03 INJUNCTION. IN RESPONSE (REF G), DOD DIRECTED IMMEDIATE RESUMPTION OF ANTHRAX VACCINATIONS IAW THE ORIGINAL GUIDANCE (REFS A, B, AND C) AND ALL SUBSEQUENT GUIDANCE RELEASED PRIOR TO 24 DEC 03 (COMPLETE LIST OF AF-WIDE GUIDANCE IS AVAILABLE AT: https://chembio.xo.hq.af.mil/bio-anthrax.shtml).
- 6. THE FOLLOWING ACTIONS ARE DIRECTED: IMMEDIATELY RESUME MANDATORY ANTHRAX VACCINATIONS FOR DESIGNATED DOD PERSONNEL IAW REF A, B, AND C FROM THE LAST DOCUMENTED VACCINATION GIVEN IN THE SERIES. DO NOT RESTART THE SERIES FROM THE BEGINNING, NOR SKIP OR REPEAT ANY VACCINATION IN THE SERIES. CONTINUE VACCINATIONS FROM THE LAST DOSE RECEIVED UNTIL THE SIX-SHOT SERIES IS COMPLETE, FOLLOWED BY ANNUAL BOOSTERS. ENSURE ALL VACCINATIONS ARE ACCURATELY RECORDED IN THE MEDICAL RECORD AND THE AIR FORCE COMPLETE IMMUNIZATION TRACKING APPLICATION (AFCITA).
- 7. MILITARY JUSTICE GUIDANCE: FOR ANTHRAX VACCINATION REFUSALS PRIOR TO 22 DEC 03 AND AFTER 7 JAN 04, DISCIPLINARY AND ADMINISTRATIVE ACTIONS MAY PROCEED IAW GUIDANCE PREVIOUSLY PROVIDED IN REFS B AND C. ENSURE SERVICE MEMBERS KNOW THAT DOD'S TEMPORARY CESSATION IS NO LONGER IN EFFECT AND THAT ORDERS TO BE VACCINATED ARE LAWFUL ORDERS. CONSULT LEGAL ADVISORS AT HIGHER HEADQUARTERS AS APPROPRIATE.
- 8. HQ USAF/XO POC FOR THIS MESSAGE IS LT COL DONNA HUDSON/XONP, 703-692-0371 (DSN 222), OR EMAIL: DONNA.HUDSON@PENTAGON.AF.MIL.