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EXECUTIVE SUMMARY

16 September 2009

(U) FDA APPROVES VACCINES FOR 2009 H1N1 INFLUENZA VIRUS. (U) (DASG-HCA) The U.S. Food and Drug Administration announced that it has approved four vaccines against the 2009 H1N1 influenza virus. The vaccines will be distributed nationally after the initial lots become available, which are expected within the next four weeks. The vaccines are made by CSL Limited, MedImmune LLC, Novartis Vaccines and Diagnostics Limited, and Sanofi Pasteur Inc. Novartis will be the main supplier of vaccine to DoD operational forces. All four companies manufacture the H1N1 vaccines using the same processes as the seasonal influenza vaccines. Based on preliminary data from adults participating in multiple clinical studies, the 2009 H1N1 vaccines induce a robust immune response in most healthy adults eight to ten days after a single dose, as occurs with the seasonal influenza vaccine. Individuals over the age of nine years will require one dose of the newly licensed vaccines; those 6 months of age to less than 10 years will require two doses separated by approximately one month. This information will immediately be included in STRATCOM and MEDCOM OPORD documents. PREPARE MEMO\_\_\_\_.

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APPROVED BY: COL Krukar

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