

MEMORANDUM

DATE: November 19, 2002
TO: VRBPAC Committee Members
CC: Rakesh Pandey, Ph.D, Douglass Pratt, MD
RE: Addendum to MedImmune Vaccines Briefing Document

The following are clarifications regarding the definitions of two effectiveness endpoints for Study AV009.

In Section 4.4 “Effectiveness in Healthy Adults”, the definitions of CDC-ILI and DOD-ILI are in error (last line of page 19 and the first line of page 20). The following revisions apply:

- (1) Revise from: “CDC-ILI was defined as fever and cough or fever and sore throat on consecutive days” to “CDC-ILI was defined as fever and cough or fever and sore throat on the same day or on consecutive days”;
- (2) Revise from: “DOD-ILI was defined as fever and cough or fever and chills on consecutive days to “DOD-ILI was defined as cough and fever or cough and chills on the same day or on consecutive days.”

The analyses in Tables 8 through 13 in the Briefing Document are correct per these revised definitions and require no revisions.