Wyeth

August 26, 2004

Mr. John Becher
Centers for Disease Control/Drug Service, D-09
1600 Clifton Road
Atlanta, GA 30333

COL John D. Grabenstein, RPh, Ph.D
Deputy Director for Military Vaccines
U.S. Army Medical Command
5111 Leesburg Pike (Suite 401)
Falls Church, VA 22041-3258

Re: STN 101106/5054 – Smallpox Vaccine Dryvax®
Extension of Dating

Dear Mr. Becher and COL Grabenstein:

Please note that Wyeth received approval on August 26, 2004 for BLA supplement 101106/5054 to extend dating from 30 to 36 months for the following lots of Smallpox Vaccine Dryvax® kits:

Lot Number	New Expiration Date
4020071	February 2005
4020072	March 2005
4020074	April 2005
4020075	May 2005

Additional testing in accordance with the protocol filed to our license is planned and a CBE supplement will be filed to extend the expiration dating beyond 36 months, if appropriate.

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Please note that the storage period of the vaccine after reconstitution with diluent continues to be 90 days.

Sincerely yours,

Dennis J. Foley, Ph.D.

DJF:jm

cc: D. Staten (CBER)
D. Yeskey (CDC)