Wyeth

Wyeth Pharmaceuticals, Inc.
401 N. Middletown Rd.
BH-21127
Pearl River, NY 10965

Dennis J. Foley, Ph.D.
Vice President
Worldwide Regulatory Affairs

August 16, 2004

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

Re: STN 101106/5052 – Smallpox Vaccine Dryvax®
Extension of Dating

Dear Mr. Becher:

Please note that Wyeth received approval on August 13, 2004 for BLA supplement 101106/5052 to extend dating from 21 to 26 months for the following lots of Smallpox Vaccine Dryvax® kits:

Lot Number	New Expiration Date
4020077	January 2005
4020076	January 2005
4030020	February 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 26 months, if appropriate.

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

Sincerely yours,

Jack D Lee for

Dennis J. Foley, Ph.D.

DJF:jm

cc: J. Grabenstein (DOD)
D. Staten (CBER)
D. Yeskey (CDC)