

Wyeth Vaccines

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July 14, 2006

Dr. Cindy Dougherty
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 101106/5078 – Smallpox Vaccine, Dryvax[®] Extension of Dating Approval
June 30, 2006 Letter to Dougherty/Grabenstein

Dear Dr. Dougherty and COL Grabenstein:

Please note that our communication on June 30, 2006 regarding extension of dating incorrectly listed the following three lots that are for investigational use only: **4018142(302701), 4018143(303001), 4018144 (302001)**. Extension of dating of those lots was not included in the approval of BLA Supplement STN 101106/5078.

Extension of dating was approved for the following commercial lots:

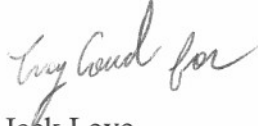
Packaged Lot (Fill Lot) 4020077 (302301), 4020076 (313701), 4030020 (313601), 4020071 (317501), 4020072 (321401), 4020074 (321301), 4020075 (317602), and 4030014 (302501) of Smallpox Vaccine Dryvax[®] through December, 2006.

Packaged Lot (Fill Lot) 4030013 (317401) of Smallpox Vaccine Dryvax[®] through October, 2006.

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

Sincerely yours,



Jack Love.

jl:ee

cc: J.Becher (ORISE Fellow)
D. Foley (AMDG Consulting LLC)
Hye-Joo Kim (CDC)
D. Staten (CBER)