DMID 01-650 PROTOCOL

A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Responses of Dryvax® Administered to Children 2 to 5 Years of Age

At the request of both the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) in a letter dated October 11, 2002, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), which is the Investigational New Drug Application (IND) Sponsor of Protocol 01-650 entitled AA Multicenter, Randomized Dose-Response Study of the Safety, Clinical and Immune Responses of Dryvax Administered to Children 2 to 5 Years of Age,@ is permitting OHRP and FDA to make available to the public the following documents: 1) Clinical Protocol Version 2.0, pages 2-51, and 2) the Investigator=s Brochure for Vaccinia Immune Globulin (VIG), cover page and pages 1-15, originally supplied by CDC. NIAID is permitting these documents to be made public because the U.S. Government owns the Dryvax product that will be evaluated in this clinical study, and there is no proprietary information in the IND documents. The public disclosure of these documents does not set a precedent for the release of similar documents for future clinical studies of investigational products conducted or sponsored by the NIAID.

10/21/2002