DEPARTMENT OF HEALTH & HUMAN SERVICES

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January 24, 2003

Dr. Stewart Laidlaw
Director, Compliance Office
Research and Education Institute
Harbor-UCLA Medical Center
1124 West Carson Street
Torrance, CA 90502-2064

Subject: Secretary's and Commissioner's Determinations on the Clinical Investigation Entitled "A Multicenter, Randomized Dose Response Study of the Safety, Clinical and Immune Responses of Dryvax® Administered to Children 2 to 5 Years of Age"

Dear Dr. Laidlaw:

This letter is written on behalf of the Office for Human Research Protections (OHRP), Department of Health and Human Services (HHS), and the Food and Drug Administration (FDA), as follow up to our phone conversation on December 20, 2002.

In August 2002, your institution forwarded the above-referenced protocol to OHRP for consideration pursuant to requirements of the HHS regulations at 45 CFR 46.407 (i.e., research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children). Because the above-referenced clinical investigation would have been regulated by FDA, FDA's regulations at 21 CFR Part 50, Subpart D, were applicable as well. In accordance with 45 CFR 46.407 and 21 CFR 50.54, HHS and the FDA solicited opinions regarding the proposed study from experts in relevant disciplines as well as from the public. The public comment period ended on December 2, 2002.

Since initiating this regulatory review process, however, bioterrorism preparedness plans have evolved such that, under current plans, the potential to use diluted Dryvax® in children will no longer exist. In the absence of plans to use diluted Dryvax® in children, the Secretary, HHS, and the Commissioner, FDA, have determined that there is no justification for this particular clinical investigation to proceed. Please note that this determination applies only to the above-referenced study involving Dryvax® in children, and does not pertain to future research involving smallpox vaccines in children.

Please do not hesitate to contact us with any questions. Thank you for your continuing commitment to the protection of human subjects.

Sincerely,

Irene Stith-Coleman, Ph.D.
Director
Division of Policy, Planning and Special Projects
Office for Human Research Protections

David A. Lepay, M.D., Ph.D.
Senior Advisor for Clinical Science and
Director, Good Clinical Practice Programs
U. S. Food and Drug Administration

cc: Dr. Carole Heilman, NIH
Dr. Pamela McInnes, NIH
Dr. Irwin Light, Chair, Cincinnati Children's Medical Center IRB
Dr. Eric Macy, Chair, Kaiser Permanente Southern California IRB