



Department of Regulatory Affairs

10390 Pacific Center Court • San Diego, CA 92121-4340

858.646.1117 • FAX: 858.334.1497

May 19, 2005

Herbert A. Smith, Ph.D.
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 2005D-0047

Dear Dr. Smith:

Vical Incorporated hereby submits comments to the draft Guidance for Industry "Considerations for Plasmid DNA Vaccines for Infectious Disease Indications". We have included the entire text of the draft guidance document for reference. Our comments follow each paragraph in bold and italic text. Please feel free to contact me at (858) 646-1117 or by email if you have any questions.

Regards,

William H. Cover, Ph.D.
Associate Director, Regulatory Affairs
Vical Incorporated
email: wcover@vical.com