DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY - 7 2002

Carlton H. Hazlewood, Ph.D.
Chairman
Burzynski Research Institute IRB
9432 Old Katy Road, Suite 370
Houston, Texas 77055

Dear Dr. Hazlewood:

Between February 12 and 15, 2002, Mr. Joel Martinez and Mr. Patrick D. Stone,investigators with the Food and Drug Administration (FDA), inspected the Institutional Review Board (IRB) at the Burzynski Research Institute. The purpose of this inspection was to determine whether your procedures for the protection of human subjects complied with Title 21 of the Code of Federal Regulations (CFR), Parts 50 and 56. These regulations apply to clinical studies of products regulated by FDA.

Based on our evaluation of the inspection report and the documents supplied during the inspection, we conclude that no significant deviations from FDA regulations or acceptable standards of good clinical practice were observed during the inspection.

We appreciate the cooperation shown our personnel during the inspection. Should you wish to discuss our review of your IRB procedures or other aspects of the protection of human subjects of research, please contact me by letter at the address noted below.

Sincerely yours,

John R. Martin, M.D.
Associate Director
for Human Subject Protection
Division of Scientific Investigations, HFD-45
Office of Medical Policy
Center for Drug Evaluation and Research
7520 Standish Place, Room 102
Rockville, Maryland 20855