DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Carlton F. Hazlewood, Ph.D.
Chairman
Burzynski Research Institute IRB
9432 Katy Freeway #370
Houston, TX 77055-6349

Dear Dr. Hazlewood:

We acknowledge receipt of your correspondence dated October 28, 2009 and November 30, 2009, in response to our Warning Letter of October 5, 2009, regarding observations made during our inspection of Burzynski Research Institute (BRI) IRB conducted between December 3 and 10, 2008.

We trust that the actions described in your letters will provide adequate measures to bring BRI IRB into compliance with FDA regulations for the protection of research subjects as described in 21 CFR Parts 50 and 56; however, we wish to remind the IRB of the following issues:

1. As stated in the October 5, 2009 Warning Letter, the IRB must report to FDA any instance of serious or continuing noncompliance with FDA regulations or the requirements or determinations of the IRB as required by 21 CFR 56.108(b)(2).

2. The IRB may want to consider developing a program to educate members on the elements of informed consent that are required by 21 CFR 50.25(a). These elements must be included in all informed consent documents that are approved by the IRB for FDA-regulated research studies.

3. In the proposed corrective actions for Observation 3, you state that (b) (4) (b) (4) will be correctly identified as the clinical investigator on the consent form for the (b) (4) study. We wish to inform you that (b) (4) . Therefore, the IRB may not approve any FDA-regulated research studies in which (b) (4) is identified as the clinical investigator. Details on (b) (4) can be found at:

(b) (4)

Finally, as discussed in our telephone conversation of December 7, 2009, we remind you of a regulation that was not in effect at the time of the BRI IRB inspection. 21 CFR §56.106 requires "Each IRB in the United States that reviews clinical investigations regulated by FDA under section 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site

maintained by the Department of Health and Human Services (HHS)." Our search of the IRB registry was unable to find BRI IRB on the list of active IRBs. Each IRB may register electronically through http://ohrp.cit.nih.gov/efile or in writing at:

Good Clinical Practice Program (HF-34)
Office of Science and Health Coordination
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Guidance on the IRB registration process can be found at:
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM171256.pdf.

Please note that at the appropriate time, FDA will conduct additional inspections to ensure that the corrective actions specified in your letters have been implemented and are effective in bringing the BRI IRB into compliance. Should you have any questions or concerns regarding this letter or the inspection, please contact me by letter at the address given below. Any written response and all correspondence will be included as a permanent part of your file.

Sincerely yours,

{See appended electronic signature page}

Kevin A. Prohaska, D.O., M.P.H.
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/s/

KEVIN A PROHASKA
12/14/2009