DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/03/2008 - 12/10/2008
	FEI NUMBER 1000220451

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Carlton F. Hazlewood, Ph.D., IRB Chairman

FIRM NAME	STREET ADDRESS
Burzynski Research Institute / IRB	9432 Katy Freeway # 370
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Houston, TX 77055-6349	IRB

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A clinical investigation requiring prior submission to the FDA was initiated without IRB approval.

Specifically, On February 01, 2008 The BRI IRB was presented with study protocol #(b) (4) entitled [redacted] (b) (4) [redacted] (b) (4) by (b) (4) M.D., Principal Investigator (P.I.) and Carlton F. Hazelwood, Ph.D., Co-P.I. Fifteen human subjects' were entered into protocol #(b) (4) under pilot case reports between January and February 2007 without an effective FDA Investigational New Drug number. On February 15, 2008 the BRI IRB approved the protocol to begin human accrual.

OBSERVATION 2

The IRB does not conduct continuing review of research at intervals of not less than once per year.

Specifically;

A) Clinical protocol entitled [redacted] (b) (4) [redacted] (b) (4) [redacted] was not reviewed & approved by the IRB annually from 2006 through 2008. In addition there are no continuing review reports on file from the P.I. to the IRB.

B) Clinical Device Protocol #(b) (4) entitled [redacted] (b) (4) [redacted] (b) (4) [redacted] conducted by Carlton F. Hazelwood, Ph.D., Co-P.I. was not reviewed & approved by the IRB annually from 2005 through 2008. In addition there are no continuing review reports on file from the P.I. to the IRB.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Patrick D Stone, Investigator PDS	12/10/2008

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OBSERVATION 3

Copies have not been maintained of all research proposals reviewed.

Specifically, ;
A) The Investigators Brochure for study protocol #(b) (4) was not found in the BRI IRB study records.
B) The device description or detailed information regarding the (b) (4) device (Protocol #(b) (4 was not found in the BRI IRB study records.

OBSERVATION 4

Documentation has not been maintained of written procedures for the IRB, as required by 21 CFR 56.108(a) and (b).

Specifically, The BRI IRB written procedures section 4.2.2.1 states that "These policies and Procedures (SOPs) will be reviewed annually". The SOPs were not reviewed from 2003 through 2008.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Patrick D Stone, Investigator	DATE ISSUED 12/10/2008