DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Centeral Expwy., Suite 300 Dallas, TX. 75204 (214) 253-5200	2/12-15/02
	FEI NUMBER 1000220451

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

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

FIRM NAME	STREET ADDRESS
Burzynski Research Institute IRB	9432 Old Katy Rd. Suite 370
CITY, STATE AND ZIP CODE Houston, TX. 77055	TYPE OF ESTABLISHMENT INSPECTED Institutional Review Board

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1. Protocol [redacted] received tentative IRB approval on 9-16-99 and then received final IRB approval on 10-28-99. The IRB has failed to keep a copy of the [redacted] protocol and informed consent form

2. While the [redacted] study received final IRB approval on 10-28-99, it has not (to date) received any progress reports from the principal investigator.

3. While the [redacted] study protocol was removed from the IRB's list of active studies, there is no final report from the principal investigator to show that the [redacted] study was terminated and to assure that all reports of injuries/SAE's were reported during the conduct of the [redacted] study.

4. The IRB issued a provisional approval for the special exception (compassionate exception) request of [redacted] however, it failed to assure that FDA approval was obtained by the principal investigator prior to commencement of treatment.

5. The IRB accepted 2 special exception requests, one that is unsigned [redacted] and one signed by a research associate ([redacted] instead of being signed by the principal investigator or co-investigator.

6. There is no record that the IRB reviewed and approved the following protocols: [redacted] and [redacted]

7. Special Exceptions receive provisional approval via expedited review exercised by the chairperson or co-chair. The BRI's IRB SOP 3, (3.4 Expedited Review) does not provide a provision for such provisional approvals.

8. A letter dated 3-30-01 states that the IRB reviewed the new pump, [redacted] Pump Model [redacted] and full board approval was granted on 3-29-01. The meeting minutes dated 3-29-01 do not document full board review and final voting results of approval.

9. Expedited review approval was given to a change in protocol and informed consent form for study [redacted] The revised protocol and informed consent form are not on file.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Joel Martinez, Investigator Patrick D. Stone, Investigator	2-15-02