DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| US Food and Drug Administration<br>Rm. 900 US Customhouse, 2nd and Chestnut Sts.<br>Phila. PA 19106 (215) 597-4390 | 4/19,20, 23-30, 5/1-4,7, 10/2001 |
| | FEI NUMBER<br>2531320 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Herbert J. Nevyas MD

| FIRM NAME | STREET ADDRESS |
|---|---|
| Medical Director | 2 Bala Plaza, 333 City Ave |
| CITY, STATE AND ZIP CODE<br>Bala Cynwyd PA 19004 | TYPE OF ESTABLISHMENT INSPECTED<br>Sponsor/Clinical Investigator |

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following observations refer to the Investigational Device Exemption [redacted] for the indicated study, [redacted]

1. There was no documentation to show that the CI notified the IRB about all amendments, changes or significant deviations to the protocol [per IRB requirements] prior to implementation.

   For example, the FDA granted your firm an increase in the number of subjects you could treat with your investigational device on Jan. 20, 1999. IRB Annual Review dated 7/29/00 does not indicate the IRB knew about population increase. The IRB did not approve the population increase until August 28, 2000, 20 months later

2. The firm is not complying with the Investigator Agreement which was signed and dated by the Clinical Investigator at the beginning of the Clinical Study.

3. There was a lapse of IRB approval for the protocol [redacted] from 8/3/2000 until 8/29/2000 according to IRB lapse notices and the IRB annual re-approval letter.

GEN. SPEC.

RELEASE

F# 01-[illegible] DATE 3/10/05

Reviewed by: [signature]

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE *(Print or Type)* | DATE ISSUED |
|---|---|---|---|
| | Ronald Stokes | Ronald Stokes | May 10, 2001 |