

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

555 Winderley Place Suite 200
Maitland, FL 32751
(407) 475-4700

DATE(S) OF INSPECTION

8/30-31/04, 9/1, 7, & 15/04

FEI NUMBER

3003017481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

to: Dr. Lisa A Krinsky, President/Director

FIRM NAME

SFBC International

STREET ADDRESS

11190 Biscayne Blvd.

CITY, STATE AND ZIP CODE

Miami, FL 33181

TYPE OF ESTABLISHMENT INSPECTED

Bioequivalence clinical facility

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

The following deviations pertain to the study involving protocol [REDACTED]

1. Failure to randomly select and retain samples from the test and reference drug products used in this bioequivalence study performed.
2. You did not always adhere to protocol requirements. Specifically,
 - a. Prior approval from the sponsor was not obtained for the use of concomitant therapy during this study, as required by the protocol. For example, subject [REDACTED] received Ibuprofen, subject [REDACTED] received Miconazole Nitrate and subject [REDACTED] received Oxygen which were not approved by the sponsor and these three subjects completed the study.
 - b. There is no documentation showing that an acceptable [REDACTED] results within one year prior to the study entry was obtained for subject [REDACTED] & subject [REDACTED] and there was no approval from the sponsor for this protocol deviation prior to the dosing of these subjects.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE



EMPLOYEE(S) NAME AND TITLE (Print or Type)

Jennifer M. Menendez
Investigator

DATE ISSUED

9/15/04