

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

555 Winderley Place Suite # 200
Maitland Florida 32761
(407) 475-4700

DATE(S) OF INSPECTION

7/20-23/04

FEI NUMBER

3003017481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Lisa A. Krinsky, President / Chairman

FIRM NAME

SFBC International

STREET ADDRESS

1190 Biscayne Blvd.

CITY, STATE AND ZIP CODE

Miami, FL 33181

TYPE OF ESTABLISHMENT INSPECTED

Bioequivalence Clinic


DURING AN INSPECTION OF YOUR FIRM, OBSERVED:

we

- 1. There is no source documentation to show that the study subjects were dosed within 5 minutes of completion of the meal when administered treatment C and treatment D.

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Jennifer M. Menendez


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

Jennifer M. Menendez Investigator
LTS6 Christopher T. Smith

DATE ISSUED

7/23/04