

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

555 Winderley Place, Suite 200
Maitland, FL 32751
(407) 475-4700 Fax: (407) 475-4768

DATE(S) OF INSPECTION

03/29/2005 - 05/02/2005*

FEI NUMBER

3003017481

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Lisa A. Krinsky, President

FIRM NAME

SFBC International Inc.

STREET ADDRESS

11190 Biscayne Blvd

CITY, STATE, ZIP CODE, COUNTRY

Miami, FL 33181-3405

TYPE ESTABLISHMENT INSPECTED

Bioresearch clinical facility

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

An investigation was not conducted in accordance with the investigational plan.

Specifically:

- a. Protocol [REDACTED] states that all exercise tests [REDACTED] will use a fixed workload (i.e., the workload that was shown to achieve [REDACTED]. The source documents for [REDACTED] show that the workload for [REDACTED] on 7/18/03 was [REDACTED] and the [REDACTED] for the [REDACTED] on 7/25/03 and [REDACTED] on 7/26/03 was [REDACTED]
- b. Protocol [REDACTED] section 6.3 [REDACTED] states, [REDACTED]. The source documents for [REDACTED] show a heart rate of 169 during [REDACTED] and a heart rate of 150 during [REDACTED] which is [REDACTED] and the source documents for [REDACTED] show a heart rate of 158 during [REDACTED] and a heart rate of 121 during [REDACTED] which is [REDACTED]
- c. Protocol [REDACTED] section 8.3.3 [REDACTED] states, "[REDACTED] however, the [REDACTED] samples were not always obtained after the completion of [REDACTED]. For example, the [REDACTED] sample was obtained prior to [REDACTED] for the subjects in group 3 (subjects [REDACTED])
- d. Protocol [REDACTED] section 10 [REDACTED] states, "[REDACTED] Subject [REDACTED] was discontinued from the study at admission period 3 due to [REDACTED] however, none of the final study procedures were performed to include physical and laboratory measures.
- e. Protocol [REDACTED] section 10 [REDACTED] states, "[REDACTED] Subject [REDACTED] was discontinued from the study at admission period 3 due to [REDACTED] however, none of the final study procedures were performed to include physical and laboratory measures.
- f. Protocol [REDACTED] section 5.2 [REDACTED] states [REDACTED]

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[REDACTED]. The source documents for subjects [REDACTED] and [REDACTED] show that they did not have [REDACTED] within the [REDACTED] of the [REDACTED] standards.

g. Protocol [REDACTED] section 8.3 [REDACTED] requires [REDACTED] on Day 1. Subject [REDACTED] checked in to the clinic on 3/25/04 and had Day -1 procedures done on this day however; was not [REDACTED]

h. Protocol [REDACTED] states for [REDACTED] #3 "[REDACTED]
[REDACTED]
[REDACTED]. Subject [REDACTED] had [REDACTED] levels greater
that or equal to [REDACTED] and the source documents show that they were not using [REDACTED]

OBSERVATION 2

Failure to prepare or maintain accurate case histories with respect to observations and data pertinent to the investigation.

Specifically;

a. (Protocol [REDACTED] The source documentation for subject [REDACTED] shows that the subject had [REDACTED] on 7/18/03 [REDACTED] of the [REDACTED] however; the [REDACTED] for this [REDACTED] test was report in the case report form as [REDACTED] which is equal to [REDACTED]

b. (Protocol [REDACTED] The source documents for subject [REDACTED] show that the [REDACTED] for the [REDACTED] was [REDACTED] and the [REDACTED] used for [REDACTED] on 7/25/03 and [REDACTED] on 7/26/03 was [REDACTED] however; after receiving a Data Clarification Request the correct [REDACTED] of [REDACTED] for these [REDACTED] tests was changed to [REDACTED] and there is not justification for this change.

c. (Protocol [REDACTED] The discharge laboratory report dated 7/27/03 for subject [REDACTED] required a repeat test for [REDACTED] & [REDACTED] out of range value by the sub- investigator who reviewed the report and the laboratory tests were never repeated. According to a note to file dated 7/21/04, the subject was lost to follow up however; this subject was reported in the case report form as completing the study.

d. (Protocol [REDACTED] For subject [REDACTED] the end of [REDACTED] and the five minute [REDACTED] time for [REDACTED] on 7/18/03 were changed after receiving a Data Clarification Request however; there is no justification for these unexplained changes.

e. (Protocol [REDACTED] The source documents for subject [REDACTED] show that the subject experienced an adverse event "headache" from 12/7/04-12/9/04 which was not reported in the case report form.

f. (Protocol [REDACTED] The meal log for Day -1 12/6/04 shows that subject [REDACTED] completed their meal at 21:40 and subject [REDACTED] completed their meal at 21:48 however; the [REDACTED] for 12/6/04 was reported in the case report

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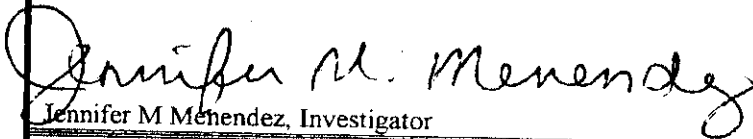
form as 22:39 for subject [REDACTED] and 22:58 for subject [REDACTED]

- g. (Protocol [REDACTED]) There is no source documentation to show that the subjects were dosed within [REDACTED] after the completion of [REDACTED] when administered [REDACTED] as required by the protocol.

* DATES OF INSPECTION:

03/29/2005(Tue), 03/30/2005(Wed), 03/31/2005(Thu), 04/05/2005(Tue), 04/06/2005(Wed), 04/07/2005(Thu), 04/08/2005(Fri),
04/11/2005(Mon), 04/12/2005(Tue), 04/19/2005(Tue), 04/20/2005(Wed), 04/21/2005(Thu), 04/22/2005(Fri), 04/25/2005(Mon),
04/26/2005(Tue), 04/27/2005(Wed), 04/28/2005(Thu), 05/02/2005(Mon)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:


Jennifer M Menendez, Investigator

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