

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

05/17/2005 - 06/03/2005*

FEI NUMBER

3004793497

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Antonio R. Pizarro, M.D., Clinical Investigator

FIRM NAME

SFBC Fort Myers

STREET ADDRESS

3745 Broadway, Suite 100

CITY, STATE, ZIP CODE, COUNTRY

Fort Myers, FL 33901-8144

TYPE ESTABLISHMENT INSPECTED

Biopharmaceutics 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

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

Specifically:

- i) Source documentation for patients [redacted] and [redacted] detailing the time between their finishing breakfast and being dosed with study medication was not available during the inspection and apparently had been lost.
- ii) Case report forms for patients [redacted] and [redacted] showed that these patients did not meet the exclusion criteria of [redacted] and these patients were included in the study, even though: patients [redacted] and [redacted] had [redacted] of [redacted] and, patient [redacted] was not listed in source documentation and had apparently not been calculated as required by the protocol.
- iii) Patients [redacted] consented on 3/1/04, [redacted] consented on 2/27/04, and [redacted] consented on 3/9/04, were not consented with the most recent approved revised version of the informed consent, dated, 1/27/04.

OBSERVATION 2

Investigational records were not retained for a period of two years following approval of a drug's marketing application and discontinuance of the investigation and notification of FDA.

Specifically, source documentation for patients [redacted] and [redacted] detailing the time between their finishing breakfast and being dosed with study medication was not available during the inspection and apparently had been lost.

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OBSERVATION 3

Failure to ensure that an investigation was conducted in accordance with the general investigational plan and protocols as specified in [REDACTED]

Specifically, patients [REDACTED] and [REDACTED] were included in the study, even though they had [REDACTED] which violated the exclusion criteria set in the protocol. And, patient [REDACTED] was included in the study, even though the patients [REDACTED] was not listed in source documentation and had apparently not been calculated as required by the protocol.

OBSERVATION 4

Informed consent was not properly documented in that the written informed consent used in the study was not approved by the IRB.

Specifically, patients [REDACTED] consented on 3/1/04, [REDACTED] consented on 2/27/04, and [REDACTED] consented on 3/9/04, were not consented with the most recent approved revised version of the informed consent, dated, 1/27/04.

*** DATES OF INSPECTION:**

05/17/2005(Tue), 05/18/2005(Wed), 05/19/2005(Thu), 05/20/2005(Fri), 05/23/2005(Mon), 05/24/2005(Tue), 05/25/2005(Wed), 05/26/2005(Thu), 06/02/2005(Thu), 06/03/2005(Fri)

FDA EMPLOYEE'S NAME, TITLE, AND SIGNATURE:

Keith A. Schwartz, Investigator

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06/03/2005