











DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street N.E. Atlanta, GA 30309 (404) 347-4001	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED to: Richard L. Borison, M.D.		PERIOD OF INSPECTION 06/09/93-06/24/93	C. F. NUMBER
TITLE OF INDIVIDUAL <i>Chairman of Dept. of Psychiatry</i>		TYPE ESTABLISHMENT INSPECTED Clinical Investigator	
FIRM NAME Uptown VA Medical Center		NAME OF FIRM, BRANCH OR UNIT INSPECTED Same, Psychiatry Service 116A-U	
STREET ADDRESS #1 Freedom Way		STREET ADDRESS OF PREMISES INSPECTED Same	
CITY AND STATE (Zip Code) Augusta, GA 30904		CITY AND STATE (Zip Code) Same	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
1. The vital sign measurements recorded in protocol 201 and 204 case report forms (CRFs) were compared with the vital sign measurements recorded in patient hospital charts (i.e. blood pressure, heart rate, temperature, and respirations). The vital signs of 5 study participants from each protocol were reviewed.			
A) On 4 occasions, vital sign measurements recorded in the CRFs were not found in the hospital charts:			
Protocol	Patient Initials	Date	
201		01/29/89 - Visit 2, Dose Rising Period	
201		05/11/89 - Visit 1, Baseline Examination	
201		07/24/89 - Visit 1, Baseline Examination	
204		07/18/90 - Visit 1, Selection	
B) On 6 occasions, at least three of the vital sign measurements recorded for a patient visit in the CRFs differed from the measurements recorded in the hospital charts.			
Protocol	Patient Initials	Date	
201		10/14/88	
201		01/23/89	
201		02/09/89	
201		02/23/89	
201		08/05/89	
204		08/07/90	
C) On 10 other occasions, at least one of the vital sign measurements recorded in the CRFs differed from the measurement recorded in the hospital chart.			
2. On Site Drug Accountability Forms for Protocol 204 do not document the return of unused study medications to the sponsor for participants 205-210.			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE <i>Stephanie E. Brewer</i>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Stephanie E. Brewer Investigator	DATE ISSUED 06/24/93

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DURING AN INSPECTION OF YOUR FIRM (I) ~~(WE)~~ OBSERVED:

3. Drug accountability records for three participants of Protocol 201 do not combine to equal the total amount of medication dispensed.

Total Dispensed by pharmacy			
	470	470	470
Total Dispensed to participant	<u>345</u>	<u>395</u>	<u>350</u>
Unused	125	75	120
Total Returned to pharmacy	117	104	86

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