



May 9, 2000

WARNING LETTER NO. 2000-NOL-22

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Benny J. Ausberry, President
Louisiana Substance Abuse Clinic, Inc.
102 Depot Street
Tallulah, Louisiana 71282

Dear Mr. Ausberry:

On February 8-16, 2000, an investigator of the U. S. Food and Drug Administration (FDA), New Orleans District, conducted an inspection of your narcotic treatment program located at 102 Depot Street, Tallulah, Louisiana.

A review of the investigator's report, including documentation collected, revealed the following significant violations of the Narcotic Treatment Standards, Title 21, *Code of Federal Regulations* (CFR), Part 291.505, Conditions For Use of Methadone:

1. Failure of the program physician to review and authorize patient admission evaluations before administering treatment, as required by Title 21, CFR, Part 291.505(d)(1)(i)(C) and Part 291.505(d)(4)(ii)(A). Examples include the following patients: [REDACTED]
2. Failure of the program physician or an authorized health care professional to provide complete medical evaluations to patients before administering treatment, as required by Title 21, CFR, Part 291.505(d)(3)(i) and Part 291.505(d)(4)(ii)(B). Examples include the following patients: [REDACTED]
3. Failure to review laboratory analyses for syphilis before administering treatment to patients, as required by Title 21, CFR, Part 291.505(d)(3)(i) and Title 21, CFR, Part 291.505(d)(4)(ii)(C). Examples include the following patients: [REDACTED]
4. Failure of an authorized health care professional to determine that patients were capable of self-administration before administering take-home medication to the same patients, as

required by Title 21, CFR, Part 291.505(d)(6)(iv)(A) and (B). Examples include the following patients: [REDACTED]

5. Failure by the Medical Director to review patient urine profiles and dosage profiles before administering treatment to patients, as required by Title 21, CFR, Part 291.505(d)(4)(ii)(C). Examples include the following patients: [REDACTED]
6. Failure to maintain records tracking lots of methadone received and dispensed, as required by Title 21, CFR, Part 291.505(d)(13)(ii);
7. Failure to notify or receive approval from the FDA before employing the services of two drug-screening laboratories, as required by Title 21, CFR, Part 291.505(d)(2)(i);
8. Failure to maintain documentation of HIV prevention and transmission counseling to patients before administering treatment, as required by Title 21, CFR, Part 291.505(d)(4)(i)(C); and,
9. Failure to ensure and document that two patients (Patient [REDACTED]) had been participating in the program for three (3) years before administering treatment on a one-time per week basis, as required by Title 21, CFR, Part 291.505(d)(4)(ii)(F) and Part 291.505(d)(6)(v)(A)(3).

This letter, as well as the "List of Observations" (Form FDA 483), which was issued and discussed with you at the close of the inspection, are not meant to be all-inclusive. It is your responsibility to insure that all provisions of Title 21, CFR, Part 291.505 are followed in the operation of your narcotic treatment program. You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action without further notice.

We acknowledge your February 22, 2000, response, which addresses the observations issued at the close of the inspection. However, your response to observations #1 and #2 above lacks sufficient detail. For example, no assurance was given to insure that admission and medical evaluations would be performed on each patient on admission to the program, as required by Title 21, CFR, Part 291.505. We request you reevaluate the listed deviations, your response, and the program's current compliance with Title 21, CFR, Part 291.505 requirements. Corrective actions presented in that response may be referenced, as appropriate, in your reply to this letter, which should include any available supporting documentation.

You should notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Asente at (504) 253-4500.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483