



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
FAX: 303-236-3100

September 21, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. Violanda T. Nunez  
Program Sponsor/Executive Director  
Ayudantes, Inc. - Northern Clinic  
1316 Apache Avenue  
Santa Fe, New Mexico 87504

Ref #: DEN-00-42

Dear Ms. Nunez:

During the period of May 5 - 24, 2000, Investigator Barbara J. White inspected your methadone maintenance clinic at 1316 Apache Avenue, Santa Fe, New Mexico.

Our review and evaluation of the investigator's report from that inspection revealed the following significant violations of the Narcotic Treatment Program Standards, Title 21, Code of Federal Regulations, Part 291.505 [21 CFR 291.505], Conditions for the Use of Narcotic Drugs:

- Failure to ensure that patient records contained Form FDA 2635 (consent form), signed at the time of admission/readmission as required under 21 CFR 291.505(d)(1)(ii). For example, consent forms were missing in charts for patients (XXXXXX XX XX XX)
- Failure of the program physician or an authorized health care professional to provide complete medical evaluations to patients before administering treatment as required under 21 CFR 291.505(d)(3)(i). For example:

Patient (XX) admitted (XX) had no medical history, tuberculosis test, nor vital signs recorded.

There are no records showing syphilis tests were performed on patients (XX) and (XX).

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Admission history and/or physicals documenting opiate abuse were not maintained for longtime patients ( X X X X X X X X )

- Failure of the primary counselor to complete Initial Treatment Plans immediately after the patient is stabilized on a dose or within 4 weeks after admission, whichever is sooner, as required under 21 CFR 291.505(d)(3)(iv)(A)(2). For example, patients ( X X X X X X ) did not have Initial Treatment Plans completed within 4 weeks of admission.
- Failure of the program physician or the primary counselor to review, reevaluate and alter where necessary each patient's Periodic Treatment Plan as required under 21 CFR 291.505 (d)(3)(v)(A). For example:

The Periodic Treatment Plan for patient ( X X ) was not reviewed at least once every 90 days during the first year of treatment and at least twice a year after the first year.

The Periodic Treatment Plans for patients ( X X X X ) were not reviewed during 1999, and only one review was documented for patient ( X X ) during the same year.

- Failure of the program physician to increase the frequency of the patient's clinic attendance for drug ingestion for at least three (3) consecutive months after the patient inexcusably missed a scheduled appointment as required under 21 CFR 291.505(d)(6)(v)(B)(1). For example, patient ( X ) missed two (2) scheduled appointments and tested positive for the presence of a drug of abuse during ( X ) ( X ). The patient was placed on daily clinic attendance for drug ingestion for three (3) days after the first missed appointment and nine (9) days after the second and was then returned to the previous schedule of three (3) visits per week.
- Failure of the person(s) responsible for the program to ensure that analyses for drugs are carried out under the conditions and frequencies required under 21 CFR 291.505(d)(2)(i). For example:

Urinalyses are not performed at least monthly for patients with six-day, take-home privileges ( X X X X X X X X )

Collection of urine samples is not well randomized as patients on six-day, take-home schedules routinely give samples on their methadone pick-up day.

Prior to December 1999, almost all drug-screening analyses were incomplete, lacking one or more of the required tests - opiates, methadone, amphetamines, cocaine, barbiturates, and drugs abused in the program's locality.

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The above noted violations and the observations listed on the Form FDA 483 issued to you at the end of the inspection are not intended to be all-inclusive. It is your responsibility as sponsor to ensure that your program comes into and remains in compliance with all federal laws and regulations.

Failure to effect prompt correction of the noted violations, or any further violations of the requirements set forth in 21 CFR 291 may result in enforcement action without further notice.

Please respond in writing within fifteen (15) days of the receipt of this letter, setting forth steps taken or being taken to correct these violations. If full corrective action has not been taken at the time of your response, please specify when it will be and explain the reason for any delay. Your reply should be directed to the attention of H. Tom Warwick, Compliance Officer, at the above letterhead address.

Sincerely,



Thomas A Allison  
District Director

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