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DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE

Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

September 25, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David L. Piccoli
Program Sponsor
Discovery House, Inc.
66 Pavilion Ave.
Providence, RI 02905

PURGED

Ref # - DEN-97-29

Dear Mr. Piccoli:

During July 16 through 25, 1997, Food and Drug Investigator Anthony E. Keller, RPH, inspected your methadone maintenance and detoxification center located at 669 South 200 East, Ste #200, Salt Lake City, Utah.

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 the tuberculin skin tests and serological tests for syphilis were performed as part of the admission physical examination for [xx] of [xx] patients whose records were reviewed [21 CFR 291.505(d)(3)(i)].
>
> The Medical director failed to ensure that the initial dose of methadone did not exceed 30 mg for at least [x] patients [21 CFR 291.505(d)(6)(i)(B)].
>
> Failure to ensure that the justification for a daily dose greater than 100 mg was documented in [x] patient records [21 CFR 291.505(d)(6)(i)(C)].
>
> Failure to ensure that patients whose dose is over 100 mg of Methadone ingest the drug under observation at least 6 days a week unless an exception for take-home medication has been approved by State Methadone Authority and FDA [21 CFR 291.505 (d)(6)(v)(D)].

Failure to document the rational in [x] of [x x] patients' records reviewed for allowing regularly scheduled take-home medications [21 CFR 291.505(d)(6)(iv)].

Failure to document the rational in [x] of [x x] patients' records reviewed for allowing exceptions to existing take-home medication schedules. [21 CFR 291.505(d)(6)(vi)(B)].

Failure to assure that take-home medication is given only to a patient who, in the reasonable clinical judgement of the physician, is responsible in handling narcotic drugs. For example, one patient, admitted to the program one year ago, was allowed a five day supply of take home medication per week. The patient record failed to include an explanation of the exceptional circumstances involved nor did it address four failed urine tests and seven unexcused absences during the same period [21 CFR 291.505(d)(6)(iv)].

The above noted violations and the observations listed on the Form FDA 483 issued to you at the termination 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 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, Acting Compliance Officer, at the above letterhead address.

Sincerely,

Gary C. Dean
Director, Denver District

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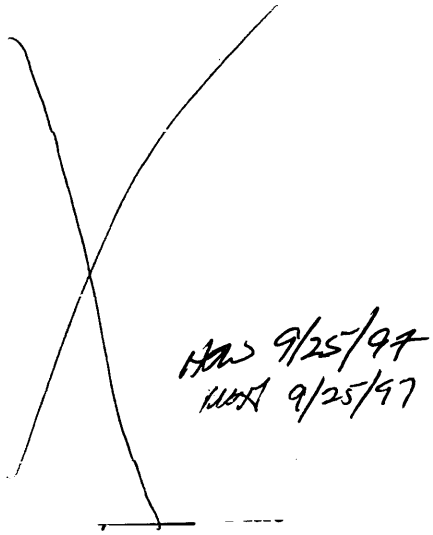
cc: F. Terry Jenkins
Program Manager
Discovery House, Utah, Inc.
Salt Lake City, UT 84111-3800

bc:



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