



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

7/1/97
EJS
D1395

January 29, 1997

WARNING LETTER
CHI-13-97

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gordon R. Lang, M.D.
Therapeutic Interventions, Inc.
Sponsor/President
1545 Hicks Road
Rolling Meadows, IL 60008

Reviewed 1/30/97 PJS

Dear Dr. Lang:

On October 10 to 16, 1996, Food and Drug Administration (FDA) Investigator Richard E. Kingdon inspected Medical Management and Detoxification (MMD) located at 1645 Hicks Road, Suites C & D, Rolling Meadows, IL 60008.

We have determined from our review and evaluation of the FDA-483, the investigators's report, and documents collected from your program during this inspection that there exists significant violations of the Narcotic Treatment Program Standards, 21 CFR 291.505, Conditions for the Use of Narcotic Drugs. They include the following:

1. You failed to assure that the initial dose of methadone for new patients does not exceed 30 mg. A review of 17 files showed that 12 patients received an initial dose of methadone that exceeded 30 mg.
2. You failed to assure that patients whose daily 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 the Illinois Department of Alcoholism and Substance Abuse (IDASA) and the FDA. A review of 11 files revealed that 8 patients, receiving daily doses of over 100 mg, were not required to ingest their medication under observation at least 6 days per week. There were no approved exceptions for these 8 patients.
3. You failed to maintain records and documentation that patients with 6-day take home privileges had monthly drug screening urinalysis for opiates, cocaine, methadone, amphetamines, and barbiturates. Our investigator found that of the 11 patient files reviewed, 10 files did not document monthly drug screening for the 10 patients.

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4. You failed to meet the minimum patient admission requirements in that patient admission evaluations did not include serological tests for syphilis. A review of 17 patient files revealed that the admission evaluations for all 17 patients lacked serological tests for syphilis.

5. You failed to assure that only patients who are responsible in handling narcotic drugs are given take-home medication. One patient, discharged September 7, 1995, was readmitted on October 2, 1995, after reportedly using street methadone. The patient was reinstated and allowed a 6-day take-home schedule.

6. You failed to label the take-home medication with the treatment center's name, address and telephone number.

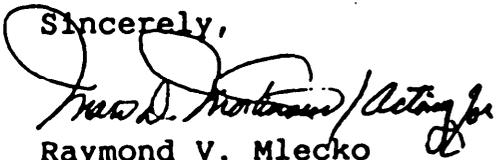
7. You failed to assure that your program physician signs or countersign all medical orders for patients. Three patient files did not include signed medical orders for the methadone pick-up schedule and the file for one patient did not include a signed medical order reducing the methadone dosage.

This letter is not intended to be all inclusive. A List of Observations (FDA 483) was issued to Bageshwari S. Parihar, Ph.D., Executive Director, at the conclusion of the inspection. A copy of the FDA 483 is enclosed. It is your responsibility to assure that your narcotic treatment program's operations are in compliance with all applicable requirements of the Act and regulations promulgated thereunder.

You should take prompt action to correct these violations. Failure to do so may result in enforcement action without further notice.

Please respond in writing within 15 days of receipt of this letter, setting forth the steps taken or being taken to correct these violations. If corrective action has not been taken at the time of your response, please specify when it will be and explain the reason for delay. Your reply should be directed to the attention of Pamela B. Schweikert, Compliance Officer, at Food and Drug Administration, 300 S. Riverside Plaza, Suite 550 South, Chicago, IL 60606.

Sincerely,


Raymond V. Mlecko
District Director

Enclosure