



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HHI-2
2/3/97
D1137B

January 29, 1997

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

WARNING LETTER
CHI-15-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Reviewed 1/30/97 PBS

Mr. Joseph Lofy, Sponsor
Vice President/New Developments
Family Guidance Centers, Inc.
737 N. LaSalle
Chicago, IL 60610

Dear Mr. Lofy:

During a Food and Drug Administration (FDA) inspection on October 22-23, 1996, of your narcotic treatment program located at the above address, our investigator documented violations of the Narcotic Treatment Program Standards, Title 21, Code of Federal Regulations (CFR), Part 291.505, Conditions for the Use of Narcotic Drugs.

Your narcotic treatment program is not operating in compliance with all regulations governing the use of narcotic drugs in the treatment of narcotic addiction. You failed to inform individuals who provide services of these regulations, and failed to monitor their activities to assure compliance with the provisions required by 21 CFR 291.505(c)(2)(i).

The specific violations are as follows:

1. You failed, as sponsor, to meet minimum patient admission requirements. For example, three of six patient admission evaluations records did not have the required tuberculin skin test.
2. You failed, as sponsor, to maintain records and documentation that patients who receive a 6-day supply of take-home medication had monthly drug screening urinalyses for opiates, cocaine, methadone, amphetamines, and barbiturates. All six patient files reviewed lacked results of monthly drug screening analyses.
3. You failed, as sponsor, to assure that the initial dose of methadone did not exceed 30 mg. A review of fifteen patient files revealed that nine patients received an initial dose of methadone that exceeded 30 mg.

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4. You failed, as sponsor, to assure that only patients who are responsible in handling narcotic drugs are given take-home medication. For example, one patient received 4 take-out doses 23 days after testing positive for opiates, and was placed on a split dosage regimen two months after the positive test.

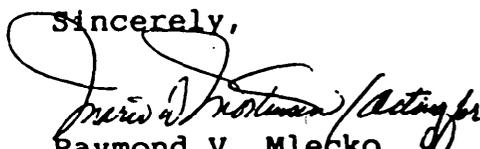
This letter is not intended to be all inclusive. A List of Observations, FDA 483 (enclosed), was issued to Mr. Anthony L. Dattomo, Program Manager, at the conclusion of the inspection. It is your responsibility, as sponsor, to assure that your program operates in compliance with all applicable regulations.

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

Please respond in writing within 15 days of receipt of this letter. Your response should describe the specific corrective action taken, including measures to prevent the recurrence of the violations, and an explanation of any expected delays in correcting the violations.

Your reply should be directed to the attention of Pamela B. Schweikert, Compliance Officer, at the above address in the letterhead.

Sincerely,


Raymond V. Mlecko
District Director

Enclosure

cc: Larry J. Kroll, Ph.D.
President & Chairman of the Board
Family Guidance Centers, Inc.
737 N. LaSalle Street
Chicago, IL 60610

cc: Mr. Anthony L. Dattomo
Program Guidance Centers, Inc. #3
751 Aurora Avenue
Aurora, IL 60505

cc: Drug Enforcement Agency