



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

HFI-35  
D1138 B

January 29, 1997

WARNING LETTER  
CHI-14-97

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ms. Deborah L. Sikorski  
Program Sponsor, FGC #1 & #2  
Vice President, Operations  
Family Guidance Centers, Inc.  
737 N. LaSalle Street  
Chicago, IL 60610

Reviewed 1/30/97 PBS

Dear Ms. Sikorski:

During an inspection of your narcotic treatment program located at 1689 Elk Boulevard, Des Plaines, IL, on October 17 to 21, 1996, our investigator found significant violations of the Narcotic Treatment Program Standards as set forth under Title 21, Code of Federal Regulations (21 CFR), 291.505, Drugs Used for Treatment of Narcotic Addicts as follows:

1. You failed to assure changes in dosage schedule were signed or countersigned by the program physician. Our investigator observed two employees increase the dispensed dosage and six take-home doses being given to a patient. The dosages were increased without a direct verbal, or telephoned, order by the program physician.
2. You failed to assure that the initial dose of methadone for new patients does not exceed 30 mg. A review of 12 files showed that 2 patients received an initial dose of methadone that exceeded 30 mg.
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. Three patient files were reviewed and revealed no documentation of monthly drug screening for two patients.
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 12 patient files revealed that the admission evaluations for all 12 patients lacked serological tests for syphilis.
5. You failed to label the take-home medication with the treatment center's name, address and telephone number.

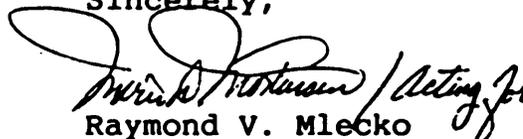
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This letter is not intended to be all inclusive. A List of Observations (FDA 483) was issued to you at the conclusion of the inspection. It is your responsibility to assure that your narcotic treatment program's operations are in compliance with all 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 FDA, 300 S. Riverside Plaza, Suite 550 South, Chicago, IL 60606.

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 60016

cc: Mr. Anthony L. Dattomo  
Program Manager  
Family Guidance Centers, Inc. #2  
1689 Elk Blvd.  
Des Plaines, IL 60016

cc: Drug Enforcement Agency