



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Nashville District Office

297 Plus Park Boulevard
Nashville, TN 37217

September 23, 1997

CERTIFIED-RETURN RECEIPT REQUESTED

Mr. Jack Randles
Program Sponsor
Volunteer Treatment Center, Inc.
2347 Rossville Boulevard
Chattanooga, TN 37408

WARNING LETTER - 97-NSV-17

Dear Mr. Randles:

During June 16 through July 2, 1997, FDA Investigator Donald E. Dodson inspected your methadone maintenance center located at 2347 Rossville Boulevard, Chattanooga, Tennessee.

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

1. Your medical director failed to assure that initial doses of methadone did not exceed 30 mg in all cases of sixteen (16) patients for whom files were reviewed. [21 CFR 291.505(d)(6)(i)(A)]
2. Your medical director administered a total daily dose of more than 40 mg of methadone, without documenting the failure of 40 mg to suppress opiate abstinence symptoms in the case of at least one patient. [21 CFR 291.505(d)(6)(i)(A)]
3. In at least one instance you permitted a patient the privilege of six (6) take-out doses of methadone per week absent the minimum requirement of 3 years consecutive comprehensive maintenance treatment. [21 CFR 291.505(d)(6)(v)(A)(3)]
4. In at least one instance you permitted a patient receiving methadone in excess of 100 mg daily take-out privileges without prior FDA or State Methadone authority approval. [21 CFR 291.505(d)(6)(v)(D)]

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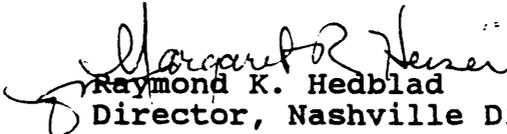
5. Your medical director frequently writes standing orders for the increase of methadone doses in increments of 5 mg every other day, and such orders are carried out by nursing personnel without a licensed physician evaluation of patient responses to preceding levels of dosage. [21 CFR 291.505(2)(6)(i)(B)]

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 remains in compliance with all federal and state laws and regulations.

Failure to effect prompt corrections 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.

We request that you respond within fifteen (15) days of receipt of this letter detailing the specific actions you intend to take, or have taken, to correct and prevent recurrence of these violations. Your response should be sent to the attention of Frank J. Jancarek, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely


Raymond K. Hedblad
Director, Nashville District

RKH/kl

cc: Drug Enforcement Agency
801 Broadway, Room 500
Nashville, TN 37203

cc: Ms. Marilyn Ressler
TN Department of Health
Health Care Facilities Services
First Floor, Cordell Hull Building
425 Fifth Avenue North
Nashville, TN 37247-0508