medication had monthly drug screening urinalyses for opiates, methadone, amphetamines, cocaine, barbiturates, and other drugs of abuse performed by a certified clinical laboratory (§ 291.505(d)(2)(i));

4. Failure to justify medication in excess of a 6-day, take-home supply given to three patients; failure to require two patients to complete 3 consecutive years of maintenance treatment at the program before being permitted to reduce their attendance for observation to once weekly; and failure to place one patient, who was receiving a 6-day supply of take-home medication, on probation for 3 months after his urinalysis was positive for a drug of abuse (§ 291.505(d)(4)(ii)(F), (d)(6)(v)(A)(3), and (d)(6)(v)(B)(2));

5. Failure of the program to have a licensed physician record, date, and sign in 2 of 13 records reviewed a change in each patient's dosage schedule (§ 291.505(d)(6)(i)(B));

6. Failure to document drug addiction and conduct physical examinations on two patients and failure to ensure that a transferring patient received a physical examination and documentation of addiction prior to administering the initial dose of methadone (§ 291.505(d)(1)(i)(C), (d)(4)(ii)(A), and (d)(4)(ii)(B));

7. Failure to ensure that the initial dose of methadone dispensed to two patients did not exceed 30 mg (§ 291.505(d)(6)(i)(A));

8. Failure of the program physician to document his review of initial drug screening urinalysis reports with his signature for two patients; and failure to document the review of random drugscreening urinalysis reports for five patients (§ 291.505(d)(2) and (d)(4)(ii)(C));

9. Failure of the program's counselors to document that three patients received counseling regarding drug-screening urinalyses that showed continued use of illicit drugs or the absence of methadone in these patients while undergoing methadone treatment (§ 291.505(d)(13)(iii));

10. Failure to obtain a signed "Consent to Treatment With an Approved Narcotic Drug" Form from two patients prior to admission to the program (§ 291.505(d)(1)(ii));

11. Failure to document that five patients received counseling on HIV disease upon admission or readmission for treatment (§ 291.505(d)(4)(i)(C));

12. Failure of the admitting physician to document his review of tuberculin skin test reports with his signature in the patient record for four patients; failure of the program physician to include the results of initial serological

tests for syphilis in the patient records for nine patients (§ 291.505(d)(3)(ii));

13. Failure of the primary counselor and/or the program physician to countersign treatment plans for eight patients; failure to properly date treatment plan for one patient; failure to have an initial treatment plan on file for readmission of one patient; and failure of the primary counselor or program physician to prepare and review the periodic treatment plan for one patient within the proper timeframes (§ 291.505(d)(3)(iv) and (d)(3)(v));

14. Failure of the program to maintain drug dispensing records that permit traceability of drug lot numbers to specific patients on those days when a change from one lot number to another occurs (§ 291.505(d)(13)(ii));

15. Failure of the program physician to document that he requested from the physician or hospital to which the program referred two pregnant patients a summary of the delivery outcome for the patients and the offspring (§ 291.505(d)(1)(iii)(B)(3) and (d)(4)(i)(B)(2)):

16. Failure to require that a patient, who had only been admitted to the program for 1 month, demonstrate adherence to the program's rules for at least 2 years before allowing the patient to decrease his personal attendance to twice weekly (§ 291.505(d)(6)(v)(A)(2)); and

(17) Failure of the program to account for, and require the return of, six extra doses of take-home medication dispensed to a patient for use during out-of-town travel that was subsequently postponed (§ 291.505(d)(13)(ii) and (d)(14)).

At the conclusion of the inspection, the FDA investigator presented a list of observations (Form FDA 483), and discussed the inspectional findings with the sponsor and his staff. The program sponsor promised to respond to the inspectional findings in writing, but has failed to do so.

II. Conclusion, Findings, and Proposed Action

As discussed above, the three most recent inspections of Carter conducted by FDA from September 12 through October 17, 1991; July 9 through July 28, 1992; and December 13, 1994, through January 24, 1995, revealed recurring violations of the Federal narcotic addiction treatment regulation, which sets forth the standards for use of narcotic drugs for medical treatment of narcotic addiction. In letters of December 14, 1991, December 9, 1992, and February 23, 1993, and during the January 6, 1993, informal conference, the sponsor made promises to correct

the violations. However, as the December 13, 1994, through January 24, 1995, inspection demonstrated, the sponsor has failed to abide by all of the narcotic addiction treatment regulations, has failed to monitor the activities of those employed in the program adequately, and has generally failed to correct the program's recurring problems.

Accordingly, as provided by § 291.505(h)(3) and (i), the Director, Center for Drug Evaluation and Research, proposed revocation of Carter's program approval to the Associate Commissioner for Regulatory Affairs. The Associate Commissioner for Regulatory Affairs has evaluated the available information and finds that the program sponsor has failed to submit adequate assurances justifying continued approval of the program.

III. Notice of Opportunity for a Hearing

Notice is hereby given to the sponsor of the Narcotic Treatment Program listed above, and to all other interested persons, that the Associate Commissioner for Regulatory Affairs, under authority delegated to him (21 CFR 5.20) proposes to issue an order under § 291.505(h)(3) revoking approval of the "Application for Approval for Use of Narcotic Drugs in a Treatment Program" (Form FDA-2632) held by The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc., 5500 North Johnson St., New Orleans, LA 70117, on the grounds stated above. In accordance with part 314 (21 CFR part 314), the sponsor is hereby given an opportunity for a hearing to show why approval should not be revoked.

The sponsor who decides to seek a hearing shall file: (1) On or before September 11, 1995, a written notice of appearance and request for a hearing, and (2) on or before October 10, 1995, information and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, submissions of data, information, and analyses to justify a hearing, other comments, and the granting or denial of a hearing are contained in § 314.200.

The failure of the applicant to file a timely written notice of appearance and request for a hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed, and a waiver of any contentions concerning the legal status of that