cocaine, methadone, amphetamines, and barbiturates in 17 of 20 patient records reviewed (§ 291.505(d)(2)(i));

4. Failure of the program to document who conducted the urinalyses in all 20 patients for which "Urinalysis Record" forms showed results of testing for methadone, opiates/opioids, and other drugs (§ 291.505(d)(2)(i) and (d)(13)(iii));

5. Failure to obtain FDA's approval of a change to an in-house laboratory for the detection of opiates and cocaine in human urine, and the failure to test patients for methadone, barbiturates, and amphetamines (§ 291.505(d)(2)(i));

6. Failure to conduct monthly urinalyses on six patients with 6-day take-home privileges (\$291.505(d)(2)(i));

7. Failure to perform initial serological tests for syphilis and tuberculin skin tests in 19 of 20 patient records reviewed (§ 291.505(d)(3)(i));

8. Failure to maintain current annual treatment plan evaluations by the program physician in 11 of 20 patient records reviewed (§ 291.505(d)(3)(v)(C));

9. Failure to record vital signs (temperature, pulse, blood pressure, and respiratory rate) as part of the admission physical examination in 14 of 20 patient records reviewed (§ 291.505(d)(3)(i));

10. Failure to ensure that the initial dose of methadone did not exceed 30 milligrams (mg) in 3 of the 20 patients whose records were reviewed (§ 291.505(d)(6)(i)(A));

11. Failure to review, reevaluate, and alter as necessary treatment plans at least once each 90 days during the first year of treatment in 4 of the 20 patient records reviewed (§ 291.505(d)(3)(v)(A));

12. Failure of the program physician to sign one patient's medication order change and to record the correct date for another patient's medication order change (§ 291.505(d)(6)(i)(B)); and

13. Failure to comply with the takehome medication requirements for 2 of the 20 patients whose records were reviewed (§ 291.505(d)(6)(iv));

At the conclusion of the inspection, the FDA investigator presented a list of observations (Form FDA 483), and discussed the findings with the sponsor and his staff. Program management attributed the violations to a lack of good recordkeeping practices and the lack of knowledge of the regulation.

FDA issued a warning letter on December 6, 1991, listing the violations. The program sponsor submitted a response on December 14, 1991, listing a number of corrective measures that had been, or would be, implemented, and pledging that the violations would not recur.

FDA and the Drug Enforcement Administration (DEA) conducted a joint inspection of the program from July 9 through July 28, 1992. This inspection revealed recurring violations in the areas of urinalyses, attendance schedules, medical orders, admission evaluations, counseling, treatment plans, and drug dispensing.

The specific violations identified in this inspection were as follows:

- 1. Failure to conduct monthly urinalyses on 5 patients with 6-day takehome privileges (\$ 291.505(d)(2)(i));
- 2. Failure of the program physician to document his review of initial drug screening reports in 5 of 10 patient records reviewed (§ 291.505(d)(1)(i)(C), (d)(2), and (d)(4)(ii)(C));
- 3. Failure to provide counseling to patients whose urinalyses showed an absence of methadone and/or continued use of drugs of abuse in 5 of 10 patient records reviewed (§ 291.505(d)(3)(v) and (d)(13)(iii));
- 4. Failure of the supervisory counselor to countersign treatment plans in 5 of 10 patient records reviewed (§ 291.505(d)(3)(iv)(C));
- 5. Failure of the program physician to record the rationale for authorizing takehome medication, and failure to record medication orders in 4 of 10 patient records reviewed (§ 291.505(d)(4)(ii)(D) and (d)(6)(iv)(A));
- 6. Failure to perform initial serological tests for syphilis in 3 of 10 patient records reviewed (§ 291.505(d)(3)(i));
- 7. Failure of program physician to ensure that initial serological tests for syphilis were reviewed in 3 of 10 patient records reviewed (§ 291.505(d)(4)(ii)(C));
- 8. Failure to perform an initial tuberculin skin test and vital signs in 1 of 10 patient records reviewed (§ 291.505(d)(3)(i)); and
- 9. Failure to maintain accurate drug dispensing records. For example, records failed to record dosages for five patients, which were given to the patients on the 31st of the month (in months with 31 days). Also, records failed to contain batch or code marks of the methadone dispensed traceable to specific patients (§ 291.505(d)(13)(ii)).

On the basis of recurring violations, FDA issued a "Proposal To Revoke Narcotic Treatment Program Approval; Notice of Informal Conference" on October 1, 1992, in accordance with § 291.505(h)(2). The October 1, 1992, notice summarized the violations observed during the last three inspections and offered the sponsor an opportunity to appear at an informal conference and explain why the program approval should not be revoked. The notice also invited the sponsor to submit a "comprehensive"

action plan" for correcting the deficiencies in the program.

The informal conference was held on January 6, 1993, at FDA's New Orleans District Office. The sponsor did not submit a comprehensive written corrective action plan at the conference. The sponsor indicated, however, that steps had been taken to make necessary corrections and that he had requested that the State and the Center for Substance Abuse Treatment (CSAT) provide technical assistance to the program. FDA's District Office gave the sponsor until February 20, 1993, to submit a written corrective action plan.

In a February 23, 1993, letter to the district office, the sponsor presented a corrective action plan and timeframes for implementation. The action plan included: (1) Installing a computerized dispensing system, (2) hiring additional personnel, and (3) obtaining a commitment for technical assistance. The sponsor asked FDA for one final opportunity to implement the recommendations of the technical assistance group.

FDA held its decision regarding revocation of approval in abeyance pending completion of the technical assistance from CSAT by June 30, 1993, and pending a reinspection of the program. FDA agreed to give the program one final opportunity to achieve regulatory compliance.

The most recent inspection of December 13, 1994, through January 24, 1995, revealed recurring violations in the areas of urinalyses, attendance schedules, medical orders, admission evaluations, counseling, treatment plans, and drug dispensing.

The specific violations were as follows:

- 1. Failure to provide the required services for two patients regarding pregnancy evaluation, prenatal counseling, and treatment outcome of the patient and offspring (§ 291.505(d)(4)(i)(B)):
- 2. Failure to document in the 13 patient records reviewed that the program physician has considered, at a minimum, the following in determining whether a patient's frequency of clinic visits for observed drug ingesting may be reduced: Absence of recent drug abuse; regularity of clinic attendance; absence of behavioral problems; absence of recent criminal activity; stability of the patient; length of time in treatment; assurance that take-home medication can be safely handled by the patient; and whether the benefits of take-outs outweigh the risks of diversion (§ 291.505(d)(6)(iv)(B));
- 3. Failure to document that two patients on 6-day, take-home