Dated: August 7, 1995.

Howard Rolston,

Director, Office of Policy and Evaluation.

[FR Doc. 95–19833 Filed 8–10–95; 8:45 am]

BILLING CODE 4184–01–P

Food and Drug Administration

[Docket No. 95N-0232]

Animal Drug Export; PERCORTEN®-V (Desoxycorticosterone Pivalate) Sterile Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed an application requesting approval for export to Canada of the animal drug Percorten®-V (desoxycorticosterone pivalate) sterile suspension for use as an injectable for dogs.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Gregory S. Gates, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Ciba-Geigy Corp., Animal Health Div., P.O. Box 18300, Greensboro, NC 27419–8300, has filed application number 6321 requesting approval for export to Canada of the animal drug Percorten®-V (desoxycorticosterone pivalate) sterile suspension. The product is intended for use in dogs as partial mineralocorticoid replacement therapy in cases of adrenocortical insufficiency. The application was received and filed in the Center for Veterinary Medicine on July 20, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by August 21, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: July 26, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–19886 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95N–0193]

The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc.; Proposal to Revoke Approval of a Narcotic Addiction Treatment Program; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revoke approval of an ''Application for Approval of Use of Methadone in a Treatment Program'' (Form FDA–2632) (renamed ''Application for Approval for Use of Narcotic Drugs in a Treatment Program'') held by The Dr. Oscar E. Carter, Jr., Memorial Rehabilitation Center, Inc. (Carter). The grounds for the proposed revocation are that the three most recent FDA inspections of the program revealed recurring violations of the Federal narcotic addiction treatment regulations, and the sponsor has failed to demonstrate adequately the ability or willingness to correct and prevent the violations. This document is intended to provide the sponsor an opportunity for a hearing to show why approval should not be revoked.

DATES: Submit a written request for a hearing by September 11, 1995; data and information in support of the hearing request by October 10, 1995.

ADDRESSES: A written request for a hearing, supporting data, and other comments should be identified with Docket No. 95N–0193 and submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerald R. Hajarian, Center for Drug Evaluation and Research (HFD–342), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1029.

SUPPLEMENTARY INFORMATION:

I. Background

On September 12, 1974, FDA granted Carter approval to operate a narcotic addiction treatment program. Such programs are governed by the rules, standards, and procedures set forth in § 291.505 (21 CFR 291.505). Since the program received approval, FDA has conducted inspections to determine the program's compliance with § 291.505. This notice will document the specific violations revealed in the three most recent inspections, and the events leading to this proposed revocation.

FDA's inspection from September 12 through October 17, 1991, revealed violations of the narcotic addiction treatment regulation 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 maintain drug dispensing records showing batch or code marks of the methadone dispensed, and failure to retain drug dispensing records for 3 years from the date of dispensing (§ 291.505(d)(13)(ii));

2. Failure to maintain methadone daily dispensing records in 5 of 20 patient records reviewed (§ 291.505(d)(13)(ii));

3. Failure to conduct initial drug screening urinalyses for opiates,

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 take-home 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 take-home 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 take-home 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

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 drug-screening 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

person's narcotic addiction treatment program.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact that precludes the revocation of approval of the application, or when a request for a hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in six copies. Except for data and information prohibited from public disclosure under 42 CFR part 2, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 4, 1995.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 95–19885 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–F

Public Health Service

Agency Forms Undergoing Paperwork Reduction Act Review

Each Friday the Public Health Service (PHS) publishes a list of information collection requests under review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the PHS Reports Clearance Office on (202) 690–7100.

The following requests have been submitted for review since the list was last published on July 21.

1. National Institutes of Health Construction Grants—42 CFR Part 52b–NPRM—New—Revised regulations governing NIH construction grants require the transfer of a facility or the owner of a facility, the use of which has changed, to provide written notice of the sale, transfer or change within 30 days. The regulations also require awardees to maintain and provide daily construction logs and provide a copy of the construction schedule; and applicants to provide cost data for projects involving the acquisition of existing facilities. *Respondents:* Federal agencies or employees, Non-profit institutions; *Number of Respondents:* 1; *Number of Responses per Respondent:* 1; *Average Burden per Response:* 1 hour; *Estimated Annual burden:* 1 hour. Send comments to Allison Eydt, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

2. AIDS Drug Discovery and Development Industry Survey—New—The National Task Force on AIDS Drug Development has identified inadequate levels of private sector activity in HIV/AIDS drug discovery targeting the human immunodeficiency virus (HIV) on molecular level as a significant obstacle to the development of new therapies. The Public Health Service is conducting this survey to determine the extent of private sector activity in this area, and to determine whether there are obstacles to further activity and collaboration in HIV/AIDS drug discovery and development between the public and private sectors. *Respondents:* Business or other for-profit; *Number of Respondents:* 300; *Number of Responses per Respondent:* 1; *Average Burden per Response:* 2 hours; *Estimated Annual burden:* 600 hours. Send comments to Allison Eydt, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503.

Written comments and recommendations concerning the proposed information collections should be sent within 30 days of this notice directly to the individual designated.

Dated: August 1, 1995.

James Scanlon,

Director, Data Policy Staff Office of the Assistant Secretary for Health and PHS Reports Clearance Officer.

[FR Doc. 95–19383 Filed 8–10–95; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 60 FR 18607, April 12, 1995) is amended to reflect a reorganization within the Office of the Director, Office of Research Services (ORS). The reorganization consists of establishing the Office of Quality Development. This reorganization is consistent with Administration objectives related to the National Performance Review and the Continuous Improvement Program. This reorganization will enable ORS to better fulfill its mission by centralizing the focus of widespread reengineering, streamlining, and quality management efforts that are currently taking place within ORS.

Section HN–B, Organization and Functions, is amended as follows: Under the heading *Office of the Director (HNAL1), Office of Research Services (HNAL)*, insert the following:

Office of Quality Development (HNAL13). (1) Provides leadership and support to ORS management in developing methods to move ORS towards a total quality culture in customer service and customer and employee satisfaction; (2) promotes quality development initiatives across ORS through management consultation, reinvention efforts, organizational redesign, total quality management, team building, strategic planning, human resource development, and effective training of managers and employees; and (3) serves as the focal point for ORS streamlining initiatives aimed at achieving downsizing targets and achieving customer satisfaction through continuous process improvement, reengineering and other organizational quality improvement methods.

Dated: July 28, 1995.

Ruth L. Kirschstein,

Deputy Director, NIH.

[FR Doc. 95–19873 Filed 8–10–95; 8:45 am]

BILLING CODE 4140–01–M

National Institutes of Health; Statement of Organizations, Functions and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 60 FR 18607, April 12, 1995), is amended to reflect the establishment of the Office of Information Systems Management (OISM) within the National Center for Human Genome Research (NCHGR). The establishment of the OISM will streamline organization within the NCHGR by bringing together all NCHGR staff with responsibility for information systems management under one umbrella organization and allow the Center to operate more effectively by making the most efficient use of manpower and resources.

Section HN-B, Organization and Functions is amended as follows: