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,