

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001N-0541]

Eduardo Caro Acevedo; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Dr. Eduardo Caro Acevedo for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Dr. Caro was convicted of a felony under Federal law for engaging in a conspiracy to defraud the United States and has demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the act relating to drug products. Dr. Caro failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective [insert date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

## FOR FURTHER INFORMATION CONTACT:

Elizabeth Sadove,  
Center for Drug Evaluation and Research (HFD-7),  
Food and Drug Administration,  
5600 Fishers Lane,  
Rockville, MD 20857,  
301-594-2041.

## SUPPLEMENTARY INFORMATION:

## I. Background

On February 16, 2001, the U.S. District Court for the District of Puerto Rico accepted Dr. Eduardo Caro Acevedo's plea of guilty to one count of conspiracy to offer and pay kickbacks in relation to the referral of Medicare beneficiaries to a durable medical equipment company, in violation of the Medicare antikickback law (42 U.S.C. 1320a-7b), and in violation of 18 U.S.C. 371. The court sentenced Dr. Caro to 2 years probation for the offense (United States v. Eduardo Caro, Docket No. 00CR020-05 (SEC) (D.P.R. July 13, 2001)).

At the time of Dr. Caro's criminal actions, he was a physician authorized to practice medicine in Puerto Rico as a Medicare provider and was authorized to prescribe, among other things, durable medical equipment to Medicare beneficiaries. The owner of a durable medical equipment company, authorized to sell to Medicare beneficiaries, offered and paid money to Dr. Caro to

unlawfully induce him to refer patients to the medical equipment company. Dr. Caro received money in return for referring patients to the company for the furnishing of durable medical equipment and services payable under the Medicare program, the specific amount depending on the value of the service or equipment referred to the company. The unlawful kickback payments made to Dr. Caro allowed the company to improperly invoice Medicare for approximately \$11,940.

In addition, Dr. Caro demonstrated a pattern of conduct sufficient to find reason to believe that he may violate requirements under the act relating to drug products. In July 2002, FDA issued Dr. Caro a Notice of Disqualification to Receive Investigational New Drugs. This action was based upon repeated and deliberate submissions of false information to drug sponsors in required reports for studies of investigational new drugs that are subject to section 505 of the act. In addition, Dr. Caro repeatedly and deliberately failed to comply with regulations governing the conduct of clinical investigators and the use of investigational new drugs in conducting two protocols sponsored by Daiichi Pharmaceutical Corp. Among other things, he submitted false information in required reports, deviated from protocols, maintained inaccurate and inadequate study records, failed to report adverse events, failed to properly account for the disposition of study medications, failed to obtain adequate

institutional review board approval, and failed to obtain proper consent from study subjects or their legally authorized representatives. As a result, he is no longer entitled to receive investigational new drugs (Notice of Disqualification to Receive Investigational New Drugs, July 30, 2002).

As a result of Dr. Caro's conviction and pattern of conduct, FDA served him by certified mail on February 18, 2004, a notice proposing to debar him for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Dr. Caro an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(b)(2)(B)(ii) of the act (21 U.S.C. 335a(b)(2)(B)(ii)), that Dr. Caro was convicted of a felony under Federal law for engaging in a conspiracy to defraud the United States and has demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the act relating to drug products. Dr. Caro was provided 30 days to file objections and request a hearing. Dr. Caro did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

## II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(b)(2)(B)(ii) of the act and under authority delegated to him (Staff Manual Guide 1410.035), finds

that Dr. Eduardo Caro Acevedo has been convicted of a felony under Federal law for engaging in a conspiracy to defraud the United States and has demonstrated a pattern of conduct sufficient to find that there is reason to believe that he may violate requirements under the act relating to drug products.

As a result of the foregoing findings, Dr. Caro is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective [insert date of publication in the FEDERAL REGISTER] (see sections 306(c)(1)(B) and (c)(2)(A)(iii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Caro, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 355b(a)(6))). If Dr. Caro, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. Caro during his period of debarment.

Any application by Dr. Caro for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2001N-0541 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed

in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: \_\_\_\_\_

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Steven K. Galson, M.D., M.P.H.  
Acting Director  
Center for Drug Evaluation  
and Research

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