

individuals specified in the application budget and Social Security Numbers, if otherwise required for individuals. The copies may include summary salary information.

#### Approved But Unfunded Applications

In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case, ACF has the option of carrying over the approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in later competition.

### VI. Award Administration Information

#### 1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

#### 2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental).

Direct Federal grants, subaward funds, or contracts under this Child Care Research Scholars Program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the prohibition of Federal funds for inherently religious activities can be found on the HHS Web site at <http://www.os.dhhs.gov/fbci/waisgate21.pdf>.

**Special Terms and Conditions of Awards:** The following special term(s) and condition(s) are in addition to the ACF standard terms and conditions which accompany the Financial Assistance Award (FAA) document.

**Conference Attendance.** The student must attend and present a poster at the Annual Meeting of the Child Care Policy Research Consortium and pre-conference each year of the grant. This conference is typically scheduled during the spring of each year. In addition, the student must attend and present at the State Administrators' Meeting typically held in the summer of each year. The budget should reflect travel funds for both conferences. Faculty advisors are strongly encouraged to attend these conferences as well.

**Archiving and Publishing.** The student must agree to archive his/her approved dissertation document with Research Connections. The student must also work with CCB staff and Research Connections staff to publish a research/policy brief that can be published on the Research Connections Web site.

#### 3. Reporting Requirements

**Program Progress Reports:** Semi-annual.

**Financial Reports:** Semi-annual.

Grantees will be required to submit program progress and financial reports (SF 269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period. The SF-269 may be found at the following URL: <http://www.acf.hhs.gov/programs/ofs/forms.htm>.

### VII. Agency Contacts

**Program Office Contact:** Dr. Dawn Ramsburg, Administration for Children and Families, Child Care Bureau, 330 C Street, SW., Switzer Building, Room 2046, Washington, DC 20447. Phone: 202-690-6705; Fax: 202-690-5600; e-mail: [dramsburg@acf.hhs.gov](mailto:dramsburg@acf.hhs.gov).

**Grants Management Office Contact:** Peter Thompson, Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, Mary E. Switzer Building, Room 2070, 330 C Street, SW., Washington, DC 20447. Phone: 202-401-4608; Fax: 202-401-5644; e-mail: [PATHompson@acf.hhs.gov](mailto:PATHompson@acf.hhs.gov).

### VIII. Other Information

Applicants will not be sent acknowledgements of received applications.

**Notice:** Beginning with FY 2006, the Administration for Children and Families will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005, applicants will be able to find a synopsis of all ACF grant opportunities and

apply electronically for opportunities via: <http://www.Grants.gov>. Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: <http://www.acf.hhs.gov/grants/index.html>.

Dated: March 14, 2005.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 05-5554 Filed 3-23-05; 8:45 am]

**BILLING CODE 4184-01-P**

## 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) debarment 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 March 24, 2005.

**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 March 24, 2005 (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: March 5, 2005.

**Steven K. Galson,**

*Acting Director, Center for Drug Evaluation and Research.*

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BILLING CODE 160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Minimally Immunogenic Germline Sequence Variants of COL-1 Antibody and Their Use

Syed Kashmiri (NCI), Eduardo Padlan (NIDDK), and Jeffrey Schlom (NCI) U.S. Provisional Application No. 60/562,781 filed 15 Apr 2004 (DHHS Reference No. E-105-2004/0-US-01) and U.S. Provisional Application No.