

c. Obtain informed client consent by explaining the risks of disclosure and the recipient's policies and procedures for preventing unauthorized disclosure;

d. Provide written assurance to this effect including copies of relevant policies; and

e. Obtain assurances of confidentiality by agencies to which referrals are made.

Assurance of compliance with these and other processes to protect the confidentiality of information will be required of all recipients. A Department of Health and Human Services (DHHS) certificate of confidentiality may be required for some projects.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I (included in the application kit).

AR98-1 Human Subjects Requirements

AR98-2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR98-9 Paperwork Reduction Act Requirements

AR98-10 Smoke-Free Workplace Requirements

AR98-11 Healthy People 2000

AR98-12 Lobbying Restrictions

AR98-13 Prohibition on Use of CDC Funds for Certain Gun Control Activities

Send all reports to: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305-2209.

I. Authority and Catalog of Federal Domestic Assistance Number

This program announcement is authorized under Sections 391, 392, 393, and 394 [42 U.S.C. 280b, 280b-1, 280b-1a, and 280b-2] of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.136.

J. Where to Obtain Additional Information

The program announcement and application forms may be downloaded from the Internet: www.cdc.gov (look under funding). You may also receive a complete application kit by calling 1-888-GRANTS4. You will be asked to identify the program announcement number and provide your name and mailing address. A complete announcement kit will be mailed to you.

Please refer to Program Announcement 98072 when you request information.

If you have questions after reviewing the forms, for business management technical assistance, contact: Joanne Wojcik, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98072, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Mailstop E-13, Atlanta, GA 30305-2209, telephone (404) 842-6796, E-mail address jcw6@cdc.gov.

For program technical assistance, contact Tim Thornton, Division of Violence Prevention, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mailstop K-60, Atlanta, GA 30341-3724, telephone, (770) 488-4646, E-mail address, tnt1@cdc.gov.

Dated: June 5, 1998.

John L. Williams,

*Director, Procurement and Grants Office
Centers, for Disease Control and Prevention
(CDC)*

[FR Doc. 98-15541 Filed 6-10-98; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0003]

Dulal C. Chatterji; Grant of Special Termination; Final Order Terminating Debarment

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) granting special termination of the debarment of Dr. Dulal C. Chatterji, 308 Dalton Dr., Raleigh, NC 27615. FDA bases this order on a finding that Dr. Chatterji provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Chatterji's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

EFFECTIVE DATE: JUNE 11, 1998.

ADDRESSES: Comments should reference Docket No. 96N-0003 and be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug

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

SUPPLEMENTARY INFORMATION:

In a **Federal Register** notice dated January 22, 1997 (62 FR 3297), Dr. Dulal C. Chatterji, cofounder, part owner, vice-president for scientific affairs, and head of the research and development (R&D) division at the generic drug manufacturer Quad Pharmaceuticals, Inc. (Quad), was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 321(dd)). The effective date of the debarment was November 1, 1995, based on Dr. Chatterji's acquiescence to debarment. The debarment was based on FDA's finding that Dr. Chatterji was convicted of a felony under Federal law for conduct relating to the development or approval of any drug product, or otherwise relating to the regulation of a drug product under section 306 of the act. On April 7, 1997, Dr. Chatterji applied for special termination of debarment under section 306(d)(4) of the act, as amended by the Generic Drug Enforcement Act.

Under section 306(d)(4)(C) and (d)(4)(D) of the act, FDA may limit the period of debarment of a permanently debarred individual if the agency finds that the debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in paragraph (a) or (b) of section 306 of the act or relating to a matter under FDA's jurisdiction. If substantial assistance is found, the extent to which debarment may be terminated will depend upon the agency's assessment of whether termination will serve the interest of justice and not threaten the integrity of the drug approval process. Special termination of debarment is discretionary with FDA.

FDA considers a determination by the Department of Justice that an individual provided substantial assistance conclusive in most cases. Dr. Chatterji fully cooperated with the Department of Justice investigations and prosecutions of others within Quad for offenses related to matters under FDA jurisdiction, as substantiated by two letters received by FDA from the U.S. Attorney's Office for the District of Maryland. Accordingly, FDA finds that Dr. Chatterji provided substantial assistance as described under section 306(d)(4)(C) of the act.

In determining whether termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, the agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that, despite the seriousness of the offense for which Dr. Chatterji was debarred, his conduct may have been an aberration, his character and scientific ability remain highly regarded by his professional peers, and that he may serve as a strong advocate for compliance with current good manufacturing practice regulations. For these reasons, the agency finds that termination of Dr. Chatterji's debarment serves the interest of justice and will not pose a threat to the integrity of the drug approval process.

Under section 306(d)(4)(D) of the act, the period of debarment of an individual who qualifies for special termination may be limited to less than permanent but to no less than 1 year. Dr. Chatterji's period of debarment has lasted more than 1 year.

Accordingly, the Deputy Commissioner for Operations, under section 306(d)(4) of the act and under authority delegated to him (21 CFR 5.20), finds that Dr. Dulal C. Chatterji's application for special termination of debarment should be granted, and that the period of debarment should terminate immediately, thereby allowing him to provide services in any capacity to a person with an approved or pending drug product application. The Deputy Commissioner for Operations further finds that because the agency is granting Dr. Chatterji's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.

As a result of the foregoing findings, Dr. Dulal C. Chatterji's debarment is terminated effective June 11, 1998 (section 306(d)(4)(C) and (d)(4)(D) of the act).

Dated: June 5, 1998.

Michael A. Friedman,

Acting Commissioner of Food and Drugs.

[FR Doc. 98-15555 Filed 6-10-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Circulatory System Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Circulatory System Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee:

To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 29 and 30, 1998, 8 a.m. to 5 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: John E. Stuhlmuller, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8243, ext. 157, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12625. Please call the Information Line for up-to-date information on this meeting.

Agenda: On June 29, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application for an external compression device used in cardiopulmonary resuscitation. On June 30, 1998, the committee will discuss and make recommendations on permanent cardiovascular implants such as heart valves and vascular grafts.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 18, 1998. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on June 29 and 30, 1998. Near the end of committee deliberations on both days, a 30-minute open public session will be conducted to address issues specific to the submission or topic before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral

presentations should notify the contact person before June 18, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 4, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-15556 Filed 6-10-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0489]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "(Petition for) Administrative Reconsideration of Action" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 26, 1998 (63 FR 14717), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0192. The approval expires on May 31, 2001.

Dated: June 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-15602 Filed 6-10-98; 8:45 am]

BILLING CODE 4160-01-F