Dated: January 15, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–1481 Filed 1–21–97; 8:45 am]

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[Docket No. 96N–0003]

Dulal C. Chatterji; 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) permanently debarring Mr. Dulal C. Chatterji, 8025 Cobble Creek Circle, Potomac, MD 20854, 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 Mr. Chatterji was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Chatterji has notified FDA that he acquiesces to debarment and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: November 1, 1995.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Mr. Dulal C. Chatterji, formerly vice-president for scientific affairs and head of the research and development (R&D) division at Quad Pharmaceuticals, Inc. (Quad), pled guilty to, and on May 12, 1994, was sentenced for, obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows:

In its new drug application (NDA) for colistimethate sodium, Quad falsely represented to FDA that it had produced three sterile batches of the drug. In fact, the firm had produced two nonsterile batches and only one sterile batch. During a subsequent FDA audit of Quad's R&D department, Mr. Chatterji directed that samples from the nonsterile batches of colistimethate sodium be destroyed.

Mr. Chatterji is subject to debarment based on a finding, under section 306(a) of the act (21 U.S.C. 355a(a)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Chatterji's conduct related to the regulation of a drug product because, in causing the destruction of drug samples, he obstructed FDA's investigation of fraudulent NDA data submitted by Quad.

In a letter received by FDA on November 1, 1995, Mr. Chatterji notified FDA of his acquiescence to debarment, as provided for in section 306(c)(2)(B) of the act. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but by acquiescing to debarment, Mr. Chatterji waived his opportunity for a hearing and any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Dulal C. Chatterji has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing findings and based on his notification of acquiescence, Mr. Dulal C. Chatterji is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective November 1, 1995, the date of notification of acquiescence (sections 306(c)(1)(B) and (c)(2)(A)(ii) 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 Mr. Chatterji, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Chatterji, 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. In addition, FDA will not accept or review any abbreviated new drug applications (ANDA's) submitted by or with the assistance of Mr. Chatterji during his period of debarment.

Any application by Mr. Chatterji for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 96N–0003 and sent to the Dockets Management Branch (address above). 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 7, 1997.

Janet Woodcock

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–1477 Filed 1–21–97; 8:45 am]

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[Docket No. 91N–0404]

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 regarding Medical Devices, Humanitarian Use Devices has been approved by the Office of Management and Budget (OMB), under the Paperwork Reduction Act of 1995. This document announces the OMB approval number.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 29, 1996 (61 FR 55804), the agency announced that the proposed information collection requirements on medical devices, humanitarian use devices (21 CFR 814.102, 814.104, 814.106. 814.108, 814.110(a), 814.112(b), 814.116(b), 814.118(d), 814.120(b), 814.124(b), 814.126(b)(i) and (ii)) had been submitted to OMB for review and clearance. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the collection of information and assigned OMB control number 0910–0332. The approval expires on November 30, 1999. Under 5 CFR 1320.5(b), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.