

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N-0412]

**Rajaram K. Matkari; Conviction Reversal; Final Order Terminating Debarment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

DMB

Display Date	6-12-00
Publication Date	6-13-00
Certifier	SNRaease

---

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order, under the Federal Food, Drug, and Cosmetic Act (the act), terminating the debarment of Rajaram K. Matkari, 1304 Riverglen Way, Berthoud, CO 80513. FDA is issuing this order because the U.S. District Court for the District of Maryland issued a Writ of Error Coram Nobis, reversing Mr. Matkari's conviction and Mr. Matkari applied for termination of his debarment on this basis.

**EFFECTIVE DATE:** *[Insert date of publication in the Federal Register.]*

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

**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 notice published in the **Federal Register** of October 20, 1993 (58 FR 54156), Rajaram K. Matkari was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application (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 21 U.S.C. 321(dd))). The debarment was based on FDA's finding that Mr. Matkari was convicted of a felony under Federal law for conduct relating to the development or approval of

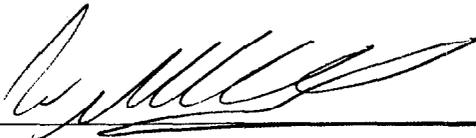
a drug product, or otherwise relating to the regulation of a drug product (section 306(a)(2)(A) and (a)(2)(B) of the act). Mr. Matkari, the former Vice President for Regulatory Affairs and Product Development of Pharmaceutical Basics, Inc. (PBI), pled guilty to and was sentenced on July 28, 1989, for giving an unlawful gratuity, a felony offense under 18 U.S.C. 201(c)(1)(A). The basis for this conviction was Mr. Matkari's payment of approximately \$2,000 to an FDA chemistry review branch chief who was responsible for supervising the chemists who reviewed PBI's applications to determine whether those applications met certain statutory standards for approval.

On February 22, 2000, the U.S. District Court for the District of Maryland issued an order granting Mr. Matkari's petition for a Writ of Error Coram Nobis in his criminal case. A copy of the court's order is available in Docket No. 92N-0412. By this order, the court reversed Mr. Matkari's conviction. On April 18, 2000, Mr. Matkari petitioned for termination of debarment under section 306(d)(3)(B)(i) of the act, as amended by the Generic Drug Enforcement Act. Section 306(d)(3)(B)(i) of the act states that "If the conviction which served as the basis for the debarment of an individual under subsection (a)(2) \* \* \* is reversed, the Secretary shall withdraw the order of debarment."

Accordingly, the Senior Associate Commissioner for Policy, Planning, and Legislation, under section 306(d)(3)(B)(i) of the act and under authority delegated to him (21 CFR 5.20), is issuing this order withdrawing the order of permanent debarment of Rajaram K. Matkari, thereby allowing

him to provide services in any capacity to a person with an approved or pending drug product application. Rajaram K. Matkari's debarment is terminated effective [*insert date of publication in the Federal Register*], (section 306(d)(3)(B)(i) of the act).

Dated: June 6, 2000  
June 6, 2000



William K. Hubbard,  
Senior Associate Commissioner  
for Policy, Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

