

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Service, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: March 5, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

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BILLING CODE 4184-01-M

Food and Drug Administration

[Docket No. 93N-0190]

Padam C. Bansal; 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. Padam C. Bansal, 9 Powelson Lane, Bridgewater, NJ 08807. FDA bases this order on a finding that Dr. Bansal has provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Bansal's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

EFFECTIVE DATE: March 11, 1997.

ADDRESSES: Comments should reference Docket No. 93N-0190 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: Diane Sullivan-Ford, Center for Drug

Evaluation and Research (HFD-7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 29, 1993 (58 FR 62674), Dr. Padam C. Bansal, the former Director of Research and Development at Par Pharmaceutical, Inc. (Par), 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), (c)(2)(A)(ii), and 201(dd) of the act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(ii), and 321(dd)). The debarment was based on FDA's finding that Dr. Bansal 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 (section 306(a)(2) of the act). On December 29, 1993, Dr. Bansal 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) of the act, FDA may limit the period of debarment of a permanently debarred individual if the agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in subsections (a) or (b) of section 306 of the act or relating to a matter under FDA's jurisdiction; (2) termination of the debarment serves the interest of justice; and (3) termination of the debarment does 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 concerning the substantial assistance of a debarred individual conclusive in most cases. Dr. Bansal fully cooperated with the Department of Justice investigations and prosecutions of others within Par, as substantiated by two letters received by FDA from the Maryland U.S. Attorney's Office. Accordingly, FDA finds that Dr. Bansal provided substantial assistance as required by section 306(d)(4)(C) of the act.

The additional requisite showings, i.e., that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process, are difficult standards to satisfy. In determining whether these have been met, 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.

Based on a thorough analysis of the available evidence, Dr. Padam C. Bansal has demonstrated that termination of his 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. Bansal'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. Padam C. Bansal'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. Bansal's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.

As a result of the foregoing findings, Dr. Padam C. Bansal's debarment is terminated, effective (*insert date of publication in the Federal Register*) (section 306(d)(4)(C) and (D) of the act).

Dated: February 27, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-5964 Filed 3-10-97; 8:45 am]

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[Docket No. 93N-0252]

Atul Shah; 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 a final order under the Federal Food, Drug, and Cosmetic Act (the act) granting special termination of the debarment of Dr. Atul Shah, 20 Hampton Hollow Dr., Perrineville, NJ 08535. FDA bases this order on a finding that Dr. Shah has