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.

[FR Doc. 97–6000 Filed 3–10–97; 8:45 am]

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]

BILLING CODE 4160–01–F

[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

provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction, and that special termination of Dr. Shah's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

EFFECTIVE DATE: March 11, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

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 a Federal Register notice dated December 5, 1994 (59 FR 62399), Dr. Atul Shah, the former Director of Analytical 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 (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 Dr. Shah 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 (21 U.S.C. 335a(a)(2)). On March 30, 1995, Dr. Shah applied for special termination of debarment, under section 306(d)(4) of the act (21 U.S.C. 335a(d)(4)), 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: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in section 306(a) or (b) 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 Dr. Shah's 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. At Dr. Shah's sentencing, the Assistant U.S. Attorney prosecuting Dr. Shah, recommended a reduced sentence based on Dr. Shah's ''substantial assistance'' to the Government in its investigation. Accordingly, FDA finds that Dr. Shah 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. Atul Shah 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. Shah's period of debarment, which commenced on December 5, 1994, 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. Atul Shah'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. Shah's application, an informal hearing under section 306(d)(4)(C) of the act is unnecessary.

As a result of the foregoing findings, Dr. Atul Shah's debarment is terminated, effective (*insert date of publication in the* Federal Register) (21 U.S.C. 335a(d)(4)(C) and (d)(4)(D)).

Dated: February 27, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–6066 Filed 3–10–97; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[Document Identifier: HCFA 668–B]

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Post Laboratory Survey Questionnaire—Laboratory, and Supporting Regulation 42 CFR section 493; *Form No.:* HCFA 668–B; *Use:* This form will allow Laboratories to assess the CLIA survey process and report their satisfaction with the survey process. This information will help HCFA evaluate the survey process from the laboratory's prospective. *Frequency:* Biennially; *Affected Public:* Federal Government, Business or other for-profit, Not-for-profit institutions, State, Local or Tribal Govt.; *Number of Respondents:* 40,000; *Total Annual Responses:* 20,000; *Total Annual Hours:* 5,000.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at http://www.hcfa.gov/regs/prdact95.htm, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human