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

Resources, Management Analysis and Planning Staff, Attention: John Rudolph, Room C2–25–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 3, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources.

[FR Doc. 97–5921 Filed 3–10–97; 8:45 am]

BILLING CODE 4120–03–P

[HCFA 3070 G–I]

Agency Information Collection Activities: Submission for OMB Review; 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, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. 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: Revision of currently approved collection; *Title of Information Collection:* Intermediate Care Facility for the Mentally Retarded or Persons with Related Conditions Survey Report Form and Supporting Regulations 42 CFR Sections 431, 435, 440, 442 and 483, Subpart I; *Form No.:* HCFA 3070 G–I; *Use:* The survey form and supporting regulations are needed to ensure provider compliance. In order to participate in the Medicaid program as an Intermediate Care Facility for the Mentally Retarded (ICF/MR), providers must meet Federal standards. The survey report form is used to record providers' compliance with the individual standard and report it to the Federal Government. *Frequency:* annually; *Affected Public:* Business or other for-profit, Not for-profit institutions, State, Local or Tribal Govt.; *Number of Respondents:* ,7200; *Total Annual Responses:* ,7200; *Total Annual Hours:* 21,600.

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 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503

Dated: February 28, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

[FR Doc. 97–6063 Filed 3–10–97; 8:45 am]

BILLING CODE 4120–03–P

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 35, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Consortia Development for Health Professions Training in Community-Based Settings—New—Consortia which include academic institutions and community-based providers have been proposed as one mechanism for improving collaboration between health professions schools and communities, enabling them to provide relevant educational experiences and facilitating meeting education and workforce goals. The consortia should be based on a formal association of academic health professions training schools or programs and community-based providers (e.g., community/migrant health centers, managed care organizations) involved, at least, in part, in the entry-level education and/or continuing education of health professionals. The purposes of this project are (1) to prepare an inventory of consortia for health professions education, (2) to examine the characteristics of successful consortia, and (3) to examine the role that consortia play in assisting health professions schools or programs to prepare health care providers for the evolving health care system.

An initial survey will be conducted by mail of consortia identified through informal conversations with key academic representatives, community-based providers, and other knowledgeable individuals, and a literature review. The initial survey will be used to gather information that generally describes the consortia, including their goals and accomplishments. Consortia respondents will also be asked to identify additional consortia that should receive the initial survey. From the information gathered in the initial survey, 20 consortia will be selected for additional study as models of successful consortia, based on criteria established by an advisory workgroup.

The second survey will consist of phone interviews with up to 20 of the consortia identified as successful models from the initial survey. These data will describe the characteristics of successful consortia in more detail (leadership, organizational models, missions and goals, financing arrangements, facilitating factors, and barriers). Data will also be collected to determine the role that consortia play in assisting health professional schools to prepare health care providers for the evolving health care system. The burden estimates are as follows: