general, and in relation to their cost, their impact on related programs, their effectiveness in targeting for services under this Act unserved older individuals with greatest economic need (including low-income minority individuals and older individuals residing in rural areas) and unserved older individuals with greatest social need (including low-income minority individuals and older individuals residing in rural areas), and their structure and mechanisms for delivery of services, including, where appropriate, comparisons with appropriate control groups composed of persons who have not participated in such programs. Evaluations shall be conducted by persons not immediately involved in the administration of the program or project evaluated''.

The purpose of this data collection is to fulfill this requirement and understand how well this program is meeting its goals and mission through the conduct of a process and outcome evaluation that is a rigorous and independent assessment of the Program's progress, efficiency and effectiveness. This information collection will enable AoA to effectively report its results to the President, to Congress, to the Department of Health and Human Services and to the public. The information will also aid in program refinement and continuous improvement.

The evaluation design is comprised of three primary components:

1. *A process study,* which examines the strategies, activities, and resources of the program at each level of the Aging Network—State Unit on Aging (SUA), Area Agency on Aging (AAA), and Local Service Provider (LSP);

2. *A cost study,* which determines the cost per meal by cost category and program type at the local service provider level; and

3. *A client outcome study,* which examines the health and social effects of the program on participants compared to non-participants. Included is an analysis of the nutrient quality of the meals provided.

The process study will include all 56 SUAs, a sample of AAAs (N=300), a sample of local service providers (N=200), and a sample of program participants and non-participants (N=2400). The SUA process component includes a short faxable data verification survey which asks the SUA to verify basic information on topics such as organization structure, staff and volunteers and population served and a survey that covers a variety of topics. The AAA process component includes a short faxable survey that focuses on program funding, staffing, and client characteristics and a web-based survey that covers a range of topics. The local service provider process component includes a short faxable survey that is comparable to the AAA faxable survey and a web-based survey that covers a range of topics. The cost study will be conducted with a sample of local service providers (including AAAs that provide direct nutrition services) and includes a data collection tool that asks about the component costs associated with meal production and delivery.

The client outcome study includes subcomponents: (1) A survey of a matched sample of program participants and non-participants and consists of an assessment of health and well-being outcomes, individual level characteristics, and program service use and quality assessments; (2) an assessment of diet quality using a 24–Hour Recall of nutrient intake; (3) a study of healthcare utilization using linked Medicare files with client data collected via the initial survey described above and brief, follow-up interviews to measure service use over the year following the initial survey; and (4) an analysis of the nutrient quality of the meals provided to program participants collected from the local service providers. Data will be collected via face-to-face interviews with the aid of Computer Assisted Personal Interview (CAPI) software. Respondents' diet quality and the nutrient content of the meals provided through the program will be measured using the USDA's Automated Multiple Pass Method (AMPM) software. Respondents will be re-contacted at 6 and 12 months via telephone with a brief survey to measure frequency of participation in the Program since the previous interview.

This information will be used by AoA to measure how well and under what circumstances does the OAA Title III–C Elderly Nutrition Services Program meet its legislative intent and goals. The proposed data collection tools may be found on the AoA Web site at *http://www.aoa.gov/AoARoot/Program_Results/Program_Evaluation.aspx.*

AoA estimates the burden of this collection of information as follows: 1,432.08 hours for organizations and 3,336.00 hours for individuals for a total of 4,768.08 hours.

Dated: April 2, 2012.

Kathy Greenlee,

Assistant Secretary for Aging.

[FR Doc. 2012–8241 Filed 4–4–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0330]

Ashish Macwan: 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 FD&C Act) debarring Ashish Macwan for 5 years 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. Macwan was convicted of one count of conspiracy to commit an offense against the United States for conduct relating to the development and approval, including the process for development and approval, of a drug product and to the regulation of drug products under the FD&C Act. In addition, the type of conduct underlying the conviction undermined the process for the regulation of drugs. Mr. Macwan was given notice of the proposed debarment and an opportunity to request a hearing within the time frame prescribed by regulation. Mr. Macwan failed to request a hearing, which constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective April 5, 2012.

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg, Rm. 4144, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds that the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product or relating to the regulation of any drug product under the FD&C Act and if FDA finds that the type of conduct that

served as the basis for the conviction undermines the process for the regulation of drugs.

On November 30, 2010, judgment was entered against Mr. Macwan in the United District Court for the District of New Jersey based upon a plea of guilty to one count of conspiracy to commit an offense against the United States, in violation of 18 U.S.C. 371.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for the conviction is as follows: Mr. Macwan was employed at Able Laboratories, Inc. (Able) as a chemist in Able's Quality Control Department from in or around mid-1999 through May 2003. In or around January 2005, Mr. Macwan was promoted to Assistant Manager in the Quality Control Department and was responsible for supervising numerous chemists, monitoring the chemists' compliance with current Good Manufacturing Practices, as required by the FD&C Act and FDA regulations. Able developed, manufactured, and sold several generic drug products, including products for cardiac and psychiatric conditions and prescription pain relievers.

From in or around 1999 through on or about May 19, 2005, Mr. Macwan conspired to cause the introduction and delivery for introduction into interstate commerce of a drug that was adulterated and misbranded, with an intent to defraud and mislead, contrary to 18 U.S.C. 371, 21 U.S.C. 331(a), and 333(a)(2).

Mr. Macwan and his coconspirators impaired, impeded, defeated, and obstructed FDA's lawful government function to approve the manufacture and distribution of generic drug products by violating Good Manufacturing Practices; violating Standards of Procedure by failing to properly investigate, log, and archive questionable, aberrant, and unacceptable laboratory results so that Able could conceal improprieties and continue to distribute and sell its drug products; manipulating and falsifying testing data and information to conceal from FDA failing laboratory results relating to Able's generic drug products; creating and maintaining false, fraudulent, and inaccurate test results to make it appear that drug products had the requisite identity, strength, quality, and purity characteristics so the drug products could be distributed and sold to increase Able's sales and profit; and creating and maintaining false, fraudulent, and inaccurate data and records to obtain FDA approval to market new product lines.

In furtherance of the conspiracy, in or around September 2003, Mr. Macwan falsified and manipulated testing data relating to the finished product testing for acetaminophen with codeine phosphate, a prescription pain relieving drug product. In addition, in or around September 2003, Mr. Macwan and his coconspirators falsified and manipulated testing data relating to the finished product testing for phentermine hydrochloride, a prescription drug developed to treat obesity.

As a result of his conviction, on December 20, 2011, FDA sent Mr. Macwan a notice by certified mail proposing to debar him for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(b)(2)(B)(i)(II) of the FD&C Act, that Mr. Macwan was convicted of a conspiracy under Federal law for conduct relating to the development and approval, including the process for development and approval of a drug product, and to the regulation of drug products under the FD&C Act, and the conduct that served as a basis for the conviction undermined the process for the regulation of drugs. The proposal also offered Mr. Macwan an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Macwan failed to request a hearing within the timeframe prescribed by regulation and, therefore, has waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR Part 12).

II. Findings and Order

Therefore, the Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(II) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Ashish Macwan has been convicted of a conspiracy under Federal law for conduct relating to the development and approval, including the process for development and approval of a drug product, and to the regulation of drug products under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermined the process for the regulation of drugs.

As a result of the foregoing finding, Mr. Macwan is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective (see **DATES**), (see sections 306(c)(1)(B), (c)(2)(A)(iii), and 201(dd) of the FD&C Act (21 U.S.C. 335a(c)(1)(B), (c)(2)(A)(iii), and 321(dd))). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Macwan, in any capacity during Mr. Macwan's debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Macwan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Macwan during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Macwan for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2009–N–0330 and sent to the Division of Dockets Management (see **ADDRESSES**). 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 2012.

Armando Zamora,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2012–8233 Filed 4–4–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0659]

Shashikant Shah: 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 FD&C Act) debarring Shashikant Shah for 5 years from