

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, Office of Public Health Preparedness and Response (BSC, OPHPR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC), announces the following meeting of the aforementioned committee:

Times and Dates: 10:30 a.m.–6 p.m., May 1, 2012; 9 a.m.–3:45 p.m., May 2, 2012.

Place: CDC, 1600 Clifton Road, NE., Roybal Campus, Atlanta, Georgia 30329. May 1, 2012: Building 19, Room 254/255. May 2, 2012: Building 21, Room 1204A/1204B.

Status: Open to the public limited only by the space available. The meeting room will accommodate up to 75 people. Public participants should pre-register for the meeting as described in Additional Information for Public Participants.

Purpose: This Board is charged with providing advice and guidance to the Secretary, Department of Health and Human Services (HHS), the Assistant Secretary for Health (ASH), the Director, Centers for Disease Control and Prevention (CDC), and the Director, Office of Public Health Preparedness and Response (OPHPR), concerning strategies and goals for the programs and research within OPHPR, monitoring the overall strategic direction and focus of the OPHPR Divisions and Offices, and administration and oversight of peer review of OPHPR scientific programs. For additional information about the Board, please visit: <http://www.cdc.gov/phpr/science/counselors.htm>.

Matters To Be Discussed: Agenda items for this meeting include: (1) Briefings and BSC deliberation on the following topics: CDC Laboratory Preparedness; OPHPR Research Portfolio Budget; CDC's Preparedness Index; Novel Approaches to Anti-Viral Delivery; CDC's Anthrax Management Team; Estimating the Cost of Preparedness; (2) Programmatic responses to BSC-approved recommendations resulting from external peer review of: The Career Epidemiology Field Officer (CEFO) Program and the Preparedness and Emergency Response Research Centers (PERRCs) program; (3) BSC liaison representative updates to the Board highlighting organizational activities relevant to the OPHPR mission; (4) a discussion of a proposed ad hoc working group to review the Division of Strategic National Stockpile (DSNS).

Agenda items are subject to change as priorities dictate.

Additional Information for Public

Participants: Members of the public that wish to attend this meeting should pre-register by submitting the following information by email, facsimile, or phone (see Contact Person for More Information) no later than 12:00 noon (EDT) on Monday, April 20, 2012:

- Full Name,

- Organizational Affiliation,
- Complete Mailing Address,
- Citizenship, and
- Phone Number or Email Address

Contact Person for More Information: Carol Marsh, OPHPR BSC Coordinator, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Mailstop D-44, Atlanta, Georgia 30333, Telephone: (404) 639-4773; Facsimile: (404) 639-7977; Email: OPHPR.BSC.Questions@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: March 30, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-8290 Filed 4-5-12; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Grant of Exclusive License: Family Healthware

AGENCY: Technology Transfer Office, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Centers for Disease Control and Prevention (CDC), Technology Transfer Office, Department of Health and Human Services (DHHS), is contemplating the grant of a worldwide, exclusive license to practice the inventions embodied in the patent application referred to below to Sanitas Inc., having a place of business in La Jolla, California. The patent rights in these inventions have been assigned to the government of the United States of America. The patent application(s) to be licensed are:

US Patent Application 11/815,445 entitled "Personal Assessment Including Familial Risk Analysis for Personalized Disease Prevention Plan," filed 5/20/2008, claiming priority to Provisional Patent Application No. 60/650,076, filed 2/3/2005. CDC Technology ID No. I-004-04.

Status: Patent Application Pending.

Priority Date: 2/3/2005.

Issue Date: N/A.

The prospective exclusive license will be royalty-bearing and will comply with

the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

Technology: This technology provides a computer-based familial risk assessment tool. It involves a three-step process which uses the disease history of a person's first and second-degree relatives to assess the risk of common diseases of adulthood in order to influence early disease detection and prevention strategies.

ADDRESSES: Requests for a copy of this patent application, inquiries, comments, and other materials relating to the contemplated license should be directed to Donald Prather, J.D., Ph.D., Technology Licensing and Marketing Specialist, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K-79, Atlanta, GA 30341, Telephone: (770) 488-8612; Facsimile: (770) 488-8615. Applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by CDC within thirty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: March 27, 2012.

Tanja Popovic,

Deputy Associate Director for Science Centers for Disease Control and Prevention.

[FR Doc. 2012-8291 Filed 4-5-12; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0332]

Jyotin Parikh: 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 Jyotin Parikh 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. Parikh 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. Parikh was given notice of the proposed debarment and an opportunity to request a hearing within the time frame prescribed by regulation. Mr. Parikh failed to request a hearing, which constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective April 6, 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 December 9, 2010, judgment was entered against Mr. Parikh 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. Parikh was employed at Able Laboratories, Inc. (Able), as Laboratory Manager in Quality Control and was later transferred to Able's Research and Development. 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. Parikh 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. Parikh and his co-conspirators 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 March 2003, Mr. Parikh supervised the creation of false and fraudulent entries in chemist laboratory notebooks, and in the corresponding process validation binders, that were used to support Able's Abbreviated new Drug Application for Lithium Carbonate Extended Release tablets, for which Able received FDA approval on or about April 21, 2003.

As a result of his conviction, on December 20, 2011, FDA sent Mr. Parikh 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 (21 U.S.C. 335a(b)(2)(B)(i)(II)) that Mr. Parikh 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. Parikh 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. Parikh failed to request a hearing within the timeframe prescribed by regulation and has, therefore, 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 Jyotin Parikh 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. Parikh 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. Parikh, in any capacity during Mr. Parikh'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. Parikh 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. Parikh during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Mr. Parikh for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2009-N-0332 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. 2012-8342 Filed 4-5-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0144]

Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information." This guidance document describes the user fees associated with 513(g) requests for information.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Bob Gatling, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1640, Silver Spring, MD 20993-0002, 301-796-6560; or
Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852. 301-796-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining FDA's views about classification information and the regulatory requirements that may be applicable to a particular device. Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA), also termed the Medical Device User Fee Amendments of 2007 (Pub. L. 110-85), extends FDA's authority to collect medical device user fees by establishing a fee for "a request for classification information."

In the **Federal Register** of April 29, 2010 (75 FR 22601), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by July 28, 2010. No comments were received. The guidance announced in this notice finalizes the draft guidance of the same title.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a document announcing the availability of a guidance document entitled "Guidance for Industry and Food and Drug Administration Staff; FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act." This guidance describes procedures for the submission, FDA review, and FDA response to requests for information with respect to the classification of a device or the requirements applicable to a device submitted in accordance with section 513(g) requests for information.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The guidance represents the Agency's current thinking on user fees for 513(g) requests for information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov> or from the CBER Internet site at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. To receive "Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information," you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8419 to receive a hard copy. Please use the document number 1709 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0705.

This guidance also refers to currently approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910-0120 and the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.