electronically at *http://www.regulations.gov*. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Lipsky, M.S. and L.K. Sharp, ''From Idea to Market: The Drug Approval Process,'' *Journal of the American Board of Family Practitioners,* vol. 14(5), pp. 362–367, 2001.

2. ''Guidance for Industry: Postmarketing Studies and Clinical Trials—Implementation of Section 505(o)(3) of the Federal Food, Drug, and Cosmetic Act,'' (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf*), 2008.

3. Rutan, G.H., R.H. McDonald, and L.H. Kuller, ''A Historical Perspective of Elevated Systolic vs. Diastolic Blood Pressure From an Epidemiological and Clinical Trial Viewpoint,'' *Journal of Clinical Epidemiology,* vol. 42(7), pp. 663–673, 1989.

4. Agency for Healthcare Research and Quality, ''Combining Measures Into Composite or Summary Scores,'' (*http://www.ahrq.gov/qual/perfmeasguide/*), 2012.

5. American Medical Association, ''Measures Development, Methodology, and Oversight Advisory Committee: Recommendations to PCPI Work Groups on Composite Measures,'' (*http://www.ama-assn.org/resources/doc/cqi/composite-measures-framework.pdf*), 2010.

6. Fagerlin, A. and E. Peters, ''Quantitative Information,'' In: B. Fishoff, N.T. Brewer, and J.S. Downs (Eds.), *Communicating Risks and Benefits: An Evidence-Based User Guide,* Food and Drug Administration, U.S. Department of Health and Human Services, (*http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm*), 2011.

7. Peters, E., D. Vastfijall, P. Slovic, et al., ''Numeracy and Decision Making,'' *Psychological Science,* vol. 17(5), pp. 407–413, 2006.

8. Gurmankin, A. D., J. Baron, and K. Armstrong, ''The Effects of Numerical Statements of Risk on Trust and Comfort With Hypothetical Physician Risk Communication,'' *Medical Decision Making,* vol. 24(3), pp. 265–271, 2004.

9. Edwards, A., R. Thomas, R. Williams, *et al.,* ''Presenting Risk Information to People With Diabetes: Evaluating Effects and Preferences for Different Formats by a Web-Based Randomized Controlled Trial,'' *Patient Education Counseling,* vol. 63, pp. 336–349, 2006.

Dated: August 17, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–20783 Filed 8–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0246]

Kelly Dean Shrum: 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) permanently debarring Kelly Dean Shrum, 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 Dr. Shrum was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. Dr. Shrum was given notice of the proposed permanent debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Shrum failed to respond. Dr. Shrum's failure to respond constitutes a waiver of his right to a hearing concerning this action.

DATES: This order is effective August 23, 2012.

ADDRESSES: Submit applications for special 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, Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On September 30, 2011, the U.S. District Court for the Eastern District of Arkansas entered judgment against Dr. Shrum for misbranding, a class A misdemeanor in violation of 21 U.S.C. sections 331(a), 333(a)(1), 352(c), and 352(f)(1), and health care fraud, a class C felony in violation of 18 U.S.C. sections 1347 and 2.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the regulation of a drug product. The factual basis for this conviction is as follows: Dr. Shrum was a licensed physician practicing in the state of Arkansas. Dr. Shrum offered gynecological and obstetric services to women, including providing forms of birth control. Dr. Shrum favored the intrauterine device (IUD) known as MIRENA, which was made for BHCP, Inc., by Bayer Schering Pharma OY (Bayer). The only version of MIRENA approved by FDA for marketing in the United States was approved on December 6, 2000, in New Drug Application 21–225.

From in or about June of 2009, in the Eastern District of Arkansas and elsewhere, Dr. Shrum purchased a foreign version of MIRENA for use in his patients that was not FDA-approved. The labeling of the unapproved IUD was not in English, and did not include adequate directions for use. Arkansas Center for Women, Ltd. was registered with the Arkansas Medicaid Program. Dr. Shrum was listed as the only physician affiliated with that clinic, and he signed the Medicaid provider contract on behalf of the Arkansas Center for Women. Dr. Shrum submitted claims to the Arkansas Medicaid Program under the clinic's provider number for the FDA-approved MIRENA IUD, which was specific to Bayer's FDA-approved product.

From on or about January 15, 2008 through on or about June 12, 2009, Dr. Shrum caused to be submitted claims for reimbursement to the Arkansas Medicaid Program, which included false representations. Specifically, he billed the Arkansas Medicaid Program as if he were administering the FDA-approved version of MIRENA, when he was actually administering a non-FDA approved IUD.

As a result of his convictions, on May 9, 2012, FDA sent Dr. Shrum a notice by certified mail proposing to permanently debar him 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(a)(2)(B) of the FD&C Act, that Dr. Shrum was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

The proposal also offered Dr. Shrum 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. The proposal was received on May 11, 2012. Dr. Shrum failed to respond and has, therefore, waived his opportunity for a hearing and has 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(a)(2)(B) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Kelly Dean Shrum has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Dr. Shrum is permanently debarred 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 section 306(c)(1)(B) and (c)(2)(A)(ii) of the FD&C Act and section 201(dd) of the FD&C Act (21 U.S.C. 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 Dr. Shrum in any capacity during Dr. Shrum's debarment, will be subject to civil money penalties (section 307(a)(6) of the Act (21 U.S.C. 335b(a)(6))). If Dr. Shrum 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 from Dr. Shrum during his period of debarment (section 306(c)(1)(B) of the FD&C Act.

Any application by Dr. Shrum for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2012–N–0246 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: August 8, 2012.

Armando Zamora,

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

[FR Doc. 2012–20784 Filed 8–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No: FDA–2012–N–0001]

Science Board to the Food and Drug Administration; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Science Board to the Food and Drug Administration (Science Board).

General Function of the Committee: The Science Board provides advice primarily to the Commissioner of Food and Drugs and other appropriate officials on specific complex scientific and technical issues important to the FDA and its mission, including emerging issues within the scientific community. Additionally, the Science Board provides advice to the Agency on keeping pace with technical and scientific developments including in regulatory science; and input into the Agency's research agenda; and on upgrading its scientific and research facilities and training opportunities. It will also provide, where requested, expert review of Agency-sponsored intramural and extramural scientific research programs.

DATES: *Date and Time:* The meeting will be held on Wednesday, October 3, 2012, from approximately 8:30 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm 1503), Silver Spring, MD 20993. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *https://collaboration.fda.gov/scienceboard/*. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm,* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Martha Monser, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4286, Silver Spring, MD 20993, 301–796–4627, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The Science Board will be presented with a draft charge to establish a new subcommittee to evaluate the Agency's continuing work to address the challenges identified in the Board's 2007 ''Science and Mission at Risk'' Report. The Science Board will be provided with updates from the Center for Devices and Radiological Health Research Review subcommittee and the Global Health subcommittee. The Science Board will also hear progress updates on nanotechnology and the ongoing activities in the priority areas outlined in the Strategic Plan for Regulatory Science. Overviews of genomics activities at the National Center for Toxological Research and the Center for Biologics Evaluation and Research will be presented. Finally, the recipients of the FY2012 Scientific Achievement awards (selected by the Science Board) will provide overviews of the activities for which the awards were given.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the