Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia) 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 findings that Ms. Chatman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. Ms. Chatman was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Ms. Chatman failed to respond. Ms. Chatman's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective April 7, 2011.

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, 5600 Fishers Lane, Rockville, MD 20857, 301–796–4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that the individual has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products 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 March 14, 2006, Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia) pleaded guilty to a misdemeanor offense of misbranding a drug. On August 14, 2006, the United States District Court for the District of Oregon entered judgment against Ms. Chatman for misdemeanor misbranding a drug, in violation of 21 U.S.C. 331(k) and 333(a)(1).

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: Ms. Chatman was a registered nurse licensed by the Oregon Board of Nursing. Throughout 2004, she assisted a codefendant in operating two clinics that offered treatments they claimed could combat the effects of aging, including injection with BOTOX. From August 2004 through December 2004, Ms. Chatman offered a botulinum toxin called "Refinex" for sale for injection to patients under the name of another drug, BOTOX. Refinex is manufactured by the Shandong Bioresearch Institute in the People's Republic of China and has never been approved or licensed by FDA for any use. Ms. Chatman misbranded a drug, namely botulinum toxin type A manufactured by Shandong Bioresearch Institute and known as Refinex, while it was held for sale and after shipment in interstate commerce, in that she offered Refinex for sale by injection to patients under the name of another drug that is approved, namely BOTOX, all in violation of 21 U.S.C. 331(k) and 333(a)(1).

As a result of her conviction, on January 5, 2011, FDA sent Ms. Chatman a notice by certified mail proposing to debar her 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)(I) of the FD&C Act, that Ms. Chatman was convicted of a misdemeanor under Federal law for conduct relating to the regulation of drug products under the FD&C Act, and that the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Ms. Chatman an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Chatman failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her 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)(I) of the FD&C Act, under authority delegated to him (Staff Manual Guide 1410.35), finds that Cathryn Lyn Chatman has been convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and that the type of conduct that served as a basis for the conviction undermines the process for the regulation of drugs.

As a result of the foregoing finding, Ms. Chatman 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. 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 Ms. Chatman, in any capacity during Ms. Chatman'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 Ms. Chatman provides services in any capacity to a person with an approved or pending drug product application during her period of debarment she 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 Ms. Chatman during her period of debarment (section 306(c)(1)(B) of the FD&C Act (21 U.S.C. 335a(c)(1)(B)). Any application by Ms. Chatman for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2010–N–0443 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 22, 2011.

Howard Sklamberg,

Director, Office of Enforcement, Office of Regulatory Affairs.

[FR Doc. 2011–8218 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Joint Meeting of the Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; 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 Committees: Cardiovascular and Renal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 2, 2011, from 8 a.m. to 4 p.m.

Location: FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center, rm. 1503, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. 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 "White Oak Conference Center Parking and Transportation Information for FDA Advisory Committee Meetings". Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Nicole Vesely, Pharm.D., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, *Fax:* 301–847–8533, *e-mail: nicole.vesely@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On May 2, 2011, the committees will discuss safety considerations of ultrasound contrast agents (materials intended to improve the clarity of ultrasound imaging), particularly related to new information and developments since the prior Advisory Committee meeting on the same topic on June 24, 2008. The discussion will include the results of required postmarketing safety studies and data from postmarketing surveillance. Specific drugs to be discussed include: (1) New drug application (NDA) 21–064, perflutren lipid microsphere injectable suspension, Lantheus Medical Imaging, Inc.; (2) NDA 20–899, perflutren protein-type A microspheres injectable suspension, GE Healthcare; and (3) the investigational new drug (IND) application for sulfur hexafluoride microbubble injection, Bracco Diagnostics, Inc. Perflutren lipid microsphere injectable suspension and perflutren protein-type A microspheres injectable suspension are indicated for use in patients with suboptimal echocardiograms to opacify the left ventricular chamber and to improve the delineation of the left ventricular endocardial border (improve the clarity of imaging of specific areas of the left lower side of the heart).

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 appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before April 18, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 8, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 11, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated March 22, 2011.

Leslie Kux,

Acting Associate Commissioner for Policy.

[FR Doc. 2011–8284 Filed 4–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Safety and Efficacy of Hypnotic Drugs; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting to discuss the safety and efficacy of drugs for the treatment of insomnia. The Division of Neurology Products (DNP) in FDA's Center for Drug Evaluation and Research and the Pharmaceutical Education and Research Institute (PERI) are cosponsoring the 2-day meeting, with the first day centered on issues of efficacy and the second day on safety.

Date and Time: The public meeting will be held on Tuesday, May 10, and Wednesday, May 11, 2011, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at the Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

Contact: Margaret Bogie, 703–276–0178, ext. 115, *Fax:* 703–276–0069; or Cathleen Michaloski, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4342, Silver Spring, MD 20993, 301–796–1123, e-mail: *Cathleen.michaloski@fda.hhs.gov.*

Accommodations: Attendees are responsible for their own accommodations. Reservations can be