

TABLE 9B.—HOSPITAL RECLASSIFICATIONS AND REDESIGNATIONS BY INDIVIDUAL HOSPITAL UNDER SECTION 508 OF PUBLIC LAW 108–173—FY 2011—Continued

CCN	Note	Geographic CBSA	Wage index CBSA section 508 reclassification	Own wage index
330106	35004	1.4341
330126	35644	1.2867
330135	35644	1.2867
330205	35644	1.2867
330264	35004	1.2529
340002	16740	0.9087
390001	10900	0.9370
390003	10900	0.9370
390045	**	10900	0.9370
390072	10900	0.9370
390095	10900	0.9370
390119	10900	0.9370
390137	10900	0.9370
390169	10900	0.9370
390185	29540	0.9852
390192	10900	0.9370
390237	10900	0.9370
390270	29540	0.9852
430005	39660	1.0934
470003	14484	1.1629
490001	31340	0.8514
530015	53	1.0577

* These hospitals are assigned a wage index value under a special exceptions policy (see FY 2005 IPPS final rule, 69 FR 49105).

** This hospital has been assigned a wage index under a special exceptions policy (see FY 2007 IPPS final rule, 71 FR 48070).

[FR Doc. 2011–8209 Filed 4–6–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

The 14th Annual Food and Drug Administration-Orange County Regulatory Affairs Educational Conference in Irvine, California: New Regulatory Challenges

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of conference.

The Food and Drug Administration (FDA) is announcing the following conference: 14th Annual Educational Conference co-sponsored with the Orange County Regulatory Affairs Discussion Group (OCRA). The conference is intended to provide the drug, device, biologics, and dietary supplement industries with an opportunity to interact with FDA reviewers and compliance officers from the centers and District Offices, as well as from other industry experts. The main focus of this interactive conference will be product approval, compliance, and risk management in the three medical product areas. Industry speakers, interactive Q & A, and

workshop sessions will also be included to assure open exchange and dialogue on the relevant regulatory issues.

Date and Time: The conference will be held on June 8 and 9, 2011, from 7:30 a.m. to 5 p.m.

Location: The conference will be held at the Irvine Marriott Hotel, 18000 Von Karman Ave., Irvine, CA 92612.

Contact: Linda Hartley, Office of Regulatory Affairs, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612, *Voice:* 949–608–4413, *Fax:* 949–608–4417; or Orange County Regulatory Affairs Discussion Group, Attention to Detail, 5319 University Dr., suite 641, Irvine, CA 92612, *Voice:* 949–387–9046, *Fax:* 949–387–9047, *Web site:* <http://www.ocra-dg.org>. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Registration and Meeting Information: See OCRA's Web site at <http://www.ocra-dg.org>. Contact Attention to Detail at 949–387–9046.

Before May 1, 2011, registrations fees are as follows: \$675.00 for members, \$725.00 for non-members and \$475.00 for FDA/Government/Students.* After May 1, 2011, \$725.00 for members, \$775.00 for non-members, and \$475.00 for FDA/Government/Students.*

* OCRA student rate applies to those individuals enrolled in a regulatory or

quality-related academic program at an accredited institution. Proof of enrollment required.

The registration fee will cover actual expenses including refreshments, lunch, materials, parking, and speaker expenses.

If you need special accommodations due to a disability, please contact Linda Hartley (*see Contact*) at least 10 days in advance.

Transcripts: Transcripts will not be available for the conference.

Dated: April 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–8283 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–2010–N–0443]

Cathryn Lyn Chatman (also known as Cathryn Lyn Garcia): 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

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 codeffendant 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]

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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