

34). Therefore, information to allow participation in the meeting through the Internet (to see the slides) and a teleconference call (capacity 50) will be provided to registered participants. Participants are encouraged to consider attending by this method. Each participant is requested to register for the free meeting by sending an e-mail to [noracoordinator@cdc.gov](mailto:noracoordinator@cdc.gov) containing the participant's name, organization name, contact telephone number on the day of the meeting, and preference for participation by Web meeting (requirements include: computer, Internet connection, and telephone, preferably with "mute" capability) or in person. An e-mail confirming registration will include the details needed to participate in the Web meeting. Non-US citizens are encouraged to participate in the Web meeting. Non-US citizens who do not register to attend in person on or before January 4, 2012, will not be granted access to the meeting site and will not be able to attend the meeting in-person due to mandatory security clearance procedures at the Patriots Plaza facility.

*Background:* NORA is a partnership program to stimulate innovative research in occupational safety and health leading to improved workplace practices. Unveiled in 1996, NORA has become a research framework for the nation. Diverse parties collaborate to identify the most critical issues in workplace safety and health. Partners then work together to develop goals and objectives for addressing those needs and to move the research results into practice. The NIOSH role is facilitator of the process. For more information about NORA, see <http://www.cdc.gov/niosh/nora/about.html>.

Since 2006, NORA has been structured according to industrial sectors. Ten major sector groups have been defined using the North American Industrial Classification System (NAICS). After receiving public input through the Web and town hall meetings, ten NORA Sector Councils have been working to define sector-specific strategic plans for conducting research and moving the results into widespread practice. During 2008–10, most of these Councils posted draft strategic plans for public comment and eight have posted finalized National Sector Agendas after considering comments on the drafts. For the National Sector Agendas, see <http://www.cdc.gov/niosh/nora/>.

**FOR FURTHER INFORMATION CONTACT:** Sidney C. Soderholm, Ph.D, NORA Coordinator, E-mail

[noracoordinator@cdc.gov](mailto:noracoordinator@cdc.gov), telephone (404) 957–0260.

Dated: October 18, 2011.

**John Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.*

[FR Doc. 2011–27627 Filed 10–24–11; 8:45 am]

**BILLING CODE 4163–19–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0084]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

**SUPPLEMENTARY INFORMATION:** On July 14, 2011, the Agency submitted a proposed collection of information entitled “Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals” to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0562. The approval expires on September 30, 2014. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: October 19, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–27532 Filed 10–24–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0159]

#### Albert Ronald Cioffi: 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) debarbing Albert Cioffi, MD 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 Dr. Cioffi 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. Dr. Cioffi was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. Dr. Cioffi failed to request a hearing. Dr. Cioffi's failure to request a hearing constitutes a waiver of his right to a hearing concerning this action.

**DATES:** This order is effective October 25, 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, Division of Compliance Policy, 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)(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 a 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 January 9, 2008, based upon a plea of guilty to one count of misbranding a drug while held for sale after shipment in interstate commerce, in violation of 21 U.S.C. 331(k), 333(a)(1), and

352(i)(3), judgment was entered against Dr. Cioffi in the United States District Court for the Southern District of Florida.

FDA's finding that debarment is appropriate is based on the misdemeanor conviction referenced herein. The factual basis for the conviction is as follows: During 2004, Dr. Cioffi was a physician licensed to practice in the State of Florida. In February 2004, Dr. Cioffi became the medical doctor of Body Rx, a medical office located in Boca Raton, FL. In July 2004, Dr. Cioffi became the sole owner of Body Rx which specialized in cosmetic procedures, including the treatment of forehead wrinkles. When Dr. Cioffi began working at Body Rx, he learned that Body Rx had been treating patients for forehead wrinkles with the unapproved drug derived from Botulinum Toxin Type A (TRI-toxin), sold by Toxin Research International (TRI), a company in Tuscon, AZ. Dr. Cioffi spoke with TRI representatives and learned that TRI-toxin was not approved by FDA for treatment of facial wrinkles. Nonetheless, Dr. Cioffi continued to purchase and use the unapproved drug from TRI. On four separate occasions between February and November of 2004, Body Rx purchased a total of eight vials of unapproved TRI-toxin at Dr. Cioffi's direction. Dr. Cioffi used the unapproved drug to inject approximately 30 patients and never informed these patients that they were receiving an unapproved version of Botulinum Toxin Type A. Instead, Dr. Cioffi told patients that they were purchasing and being injected with the approved BOTOX Cosmetic, and he indicated in these patients' medical records that they were receiving the FDA approved BOTOX Cosmetic.

From in or about February 2004, and continuing through in or about November 2004, in the Southern District of Florida, and elsewhere, Dr. Cioffi did misbrand a drug, namely Botulinum Toxin Type A distributed by TRI, while it was held for sale and after shipment in interstate commerce, in that he offered the unapproved Botulinum Toxin Type A for sale by injection to patients under the name of another drug, all in violation of 21 U.S.C. 331(k), 333(a)(1), 352(i)(3), and 18 U.S.C. 2.

As a result of his conviction, on June 1, 2011, FDA sent Dr. Cioffi 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)(I) of the FD&C Act that Dr. Cioffi was

convicted of a misdemeanor under Federal law for conduct relating to the regulation of a drug product under the FD&C Act, and the conduct that served as a basis for the conviction undermines the process for the regulation of drugs. The proposal also offered Dr. Cioffi 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. Dr. Cioffi 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 Acting 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 Albert R. Cioffi 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, Dr. Cioffi 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 Dr. Cioffi, in any capacity during Dr. Cioffi'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 Dr. Cioffi 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 Dr. Cioffi during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Any application by Dr. Cioffi for termination of debarment under section 306(d)(1) of the Act (21 U.S.C. 355a(d)(1)) should be identified with Docket No. FDA-2011-N-0159 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: October 11, 2011.

**Armando Zamora,**

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

[FR Doc. 2011-27509 Filed 10-24-11; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-D-0643]

#### Guidance for Industry on What You Need to Know About Administrative Detention of Foods; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "What You Need to Know About Administrative Detention of Foods." This guidance provides information pertaining to FDA's authority to order the administrative detention of food for human or animal consumption under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety and Modernization Act (FSMA).

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Outreach and Information Center (HFS-009), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the