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

Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William A. Correll, Jr., Office of Compliance (HFS–607), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1611.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''What You Need to Know About Administrative Detention of Foods,'' which replaces the guidance of the same title issued in November 2004. The guidance is intended to provide individuals in the human and animal food industries with an understanding of FDA's authority to order the administrative detention of human or animal food under section 304(h) of the FD&C Act (21 U.S.C. 334(h)), as amended by section 207 of FSMA. It provides practical information, including who can approve an administrative detention order, what food may be subject to administrative detention, who receives a copy of an administrative detention order, and the process for appealing an administrative detention order. Additionally, the guidance identifies references that contain more information regarding FDA's authority to order administrative detention.

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation § 10.115 (21 CFR 10.115) as a level 1 guidance. The Agency will accept comments, but it is implementing this document immediately, in accordance with § 10.115(g)(2) because the Agency has determined that prior public participation is not feasible or appropriate. The Agency made this determination because much of this guidance remains the same as the guidance issued in November 2004. In addition, this guidance simply reflects the statutory changes made by section 207 of FSMA to section 304(h)(1)(A) of the FD&C Act (21 U.S.C. 334(h)(1)(A)) and seeks to remove any confusion that might arise due to the existence of a guidance document that is inconsistent with the FD&C Act and its implementing regulations. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGPs regulation.

FSMA was signed into law on January 4, 2011. Section 207 of FSMA amended the criteria for ordering administrative detention in section 304(h)(1)(A) of the FD&C Act to provide FDA the authority to order administrative detention if there is reason to believe that an article of food is adulterated or misbranded. On May 5, 2011, in accordance with FSMA, FDA published an interim final rule in the **Federal Register** amending its regulations in part 1, subpart K (21 CFR part 1, subpart K), (76 FR 25538), that pertain to the criteria for ordering administrative detention. This interim final rule became effective on July 3, 2011.

The guidance represents the Agency's current thinking on its authority to order the administrative detention of human or animal foods. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to collections of information found in FDA regulations. These collections of information 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). We conclude that the collections of information in §§ 1.381(d) and 1.402 are exempt from OMB review under 44 U.S.C. 18(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities. The regulations in 5 CFR 1320(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit, or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the decision to detain an article of food.

III. 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. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.* Always access an FDA guidance document by using the FDA's Web site listed previously to find the most current version of the guidance.

Dated: October 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–27529 Filed 10–24–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0568]

Small Entity Compliance Guide: Required Warnings for Cigarette Packages and Advertisements; 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 ''Required Warnings for Cigarette Packages and Advertisements—Small Entity Compliance Guide'' for a final rule published in the **Federal Register** on June 22, 2011. This small entity compliance guide (SECG) is intended to set forth in plain language the requirements of the regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG entitled ''Required Warnings for Cigarette Packages and Advertisements—Small Entity Compliance Guide'' to the Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.