Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20857. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm431040.htm* approximately 45 days after the workshop.

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05017 Filed 3–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0147]

Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.'' This guidance provides information in response to questions that FDA has received from manufacturers on demonstrating the substantial equivalence of a new tobacco product, including questions on when a modification to the label requires a premarket submission and review by FDA.

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

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions'' to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. 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 information on 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002; 1–877–287–1373, *CTPRegulations@fda.hhs.gov,* email: *annette.marthaler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.'' In this guidance, FDA addresses questions from manufacturers on demonstrating the substantial equivalence of a new tobacco product. In the **Federal Register** of September 9, 2011 (76 FR 55927), FDA announced the availability of the draft guidance of the same title. After carefully reviewing and considering comments and information submitted in response to the draft guidance, which covered a range of topics on demonstrating the substantial equivalence of a new tobacco product, FDA is finalizing this guidance on many of the topics, including modifications to labels and changes to product quantity and intends to address the other topics in future regulatory documents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved information collections 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). The collections of information in sections 905(j) and 910 of the FD&C Act (21 U.S.C. 387e(j) and 387j), as amended by the Tobacco Control Act, have been approved under OMB control number 0910–0673; the collections of information in 21 CFR part 25 have been approved under OMB control number 0910–0322.

IV. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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, and will be posted to the docket at *http://www.regulations.gov.*

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.regulations.gov* or *http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm.*

Dated: February 27, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05023 Filed 3–4–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0303]

William F. DeLuca, Jr.; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Dr. William F. DeLuca, Jr. and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Dr. DeLuca 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 a finding that Dr. DeLuca 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. In determining the appropriateness and period of Dr. DeLuca's debarment, FDA has considered the relevant factors listed in the FD&C Act. Dr. DeLuca has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: The order is effective March 5, 2015.

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: Nathan Doty, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8556.

SUPPLEMENTARY INFORMATION:

I. Background

On August 11, 2009, in the U.S. District Court for the Northern District of New York, Dr. DeLuca, a physician, pled guilty to a misdemeanor under the FD&C Act, namely misbranding a drug in violation of sections 301(k), 502(i)(3), and 303(a)(1) of the FD&C Act (21 U.S.C. 331(k), 352(i)(3), 333(a)(1)) and 18 U.S.C. 2. The basis for this conviction was conduct surrounding his injection of patients seeking treatment with BOTOX/BOTOX Cosmetic (BOTOX) with a product, TRI-toxin, distributed by Toxin Research International, Inc. BOTOX is a biological product derived from Botulinum Toxin Type A that is manufactured by Allergan, Inc., and was approved by FDA for use on humans for the treatment of facial wrinkles in 1991. According to the records of the criminal proceedings, Dr. DeLuca directed a nurse to obtain 31 vials of TRI-toxin, an unapproved drug product, which was represented by its distributor as ''Botulinum Toxin Type A.'' Dr. DeLuca then proceeded to inject approximately 62 patients, who believed they were being injected with BOTOX, with TRI-toxin as a substitute.

Dr. DeLuca is subject to debarment based on a finding, under section 306(b)(2)(B)(i) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)): (1) That he was convicted of a misdemeanor under Federal law relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs. By letter dated November 30, 2010, FDA notified Dr. DeLuca of its proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application.

In a letter dated December 28, 2010, through counsel, Dr. DeLuca requested a hearing on the proposal. In his request for a hearing, Dr. DeLuca acknowledges his convictions under Federal law, as alleged by FDA. However, he argues that section 306(b)(2)(B)(i) of the FD&C Act, which was added by the Generic Drug Enforcement Act (GDEA), does not apply to him because he was never involved in the development, approval, or regulation of drug products, nor was the conduct underlying his conviction related to the development, approval, or regulation of drug products.

We reviewed Dr. DeLuca's request for a hearing and find that Dr. DeLuca has not created a sufficient basis for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

The Chief Scientist has considered Dr. DeLuca's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In support of his hearing request, Dr. DeLuca asserts that section 306(b)(2)(B)(i)(I) of the FD&C Act does not apply to him because he was never involved in the development, approval, or regulation of drug products, nor was the underlying conduct of his conviction related to those activities. He argues that application of the permissive debarment provisions to him expands the intended scope of section 306(b)(2)(b)(i)(I) of the FD&C Act beyond congressional intent. Dr. DeLuca further asserts that the statutory provision is limited to conduct that directly or indirectly affects FDA's regulatory efforts associated with drug approval, that the intended targets of GDEA are those who manufacture and distribute drugs, and that the court's decision in *Bhutani* v. *U.S. Food and Drug Administration,* 161 Fed. Appx. 589, 591 (7th Cir. 2006) and FDA's debarment order for Premchand Girdhari (65 FR 3454, January 21, 2000) also expressed this limitation. He asserts that, because his conduct did not fall within any such activities and he was not a company manufacturing or distributing drugs, but merely a physician using a drug, albeit an unapproved drug, section 306(b)(2)(B)(i)(I) if the FD&C Act is inapplicable to him.

During his criminal proceedings, Dr. DeLuca pled guilty to misbranding and causing the misbranding of a drug in violation of sections 301(k), 502(i)(3) and 303(a)(1) of the FD&C Act by offering TRI-toxin, a drug not approved for use, in place of an approved drug product, BOTOX. This conduct clearly relates to the regulation of drugs under the FD&C Act because it was in direct violation of the FD&C Act. The conduct also undermined the process for the regulation of drugs in that it permitted an unapproved drug to be substituted for an approved drug without the knowledge of the patient. As a result, Dr. DeLuca is subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

Dr. DeLuca's narrow interpretation of section 306(b)(2)(B)(i) of the FD&C Act, as well as the other provisions added to the statute by GDEA, is unpersuasive. Under well-recognized rules of statutory construction, the starting point in interpreting a statute is the text of the statute itself. (*BedRoc Limited LLC.* v. *United States,* 541 U.S. 176, 183 (2004), on remand, 368 F.3 1149 (9th Cir. 2004)). It is clear from section 306(b)(2)(B)(i) of the FD&C Act that the ''regulation of drugs'' is not limited to activities related to the approval of drugs. If that were the case, there would be no need for the language ''or otherwise relating to the regulation of drug products'' as the provision already clearly covers approval activities with the language ''relating to the development, or approval, including the process for development or approval.'' Under rules of statutory construction, all the words in a statute are to be given meaning and no words or provisions are to be rendered superfluous. (*Montclair* v. *Ramsdell,* 107 U.S. 147, 152 (1883), *Astoria Federal Savings and Loan Ass'n* v. *Solimino,* 501 U.S. 104, 112 (1991).)

Dr. DeLuca's arguments regarding the legislative history and intent of GDEA also are unpersuasive. Dr. DeLuca cites to the House Report for the bill passed by the House. However, that bill did not ultimately become section 306(b)(2)(B)(i) of the FD&C Act. If the language of the statute is clear, there is no need to look outside the statute to its

legislative history in order to ascertain the statute's meaning. (*Chamber of Commerce of United States* v. *Whiting,* 131 S. Ct. 1968 (2011).) Dr. DeLuca's conduct in misbranding Tri-toxin by holding it for sale and administering it to patients as the approved drug BOTOX clearly relates to FDA's regulation of approved drugs. Likewise, his argument that section 306(b)(2)(B)(i) of the FD&C Act could not have been intended to cover him because he did not work for a person with a pending or approved drug product application when he was convicted or that section 306(b)(2)(B)(i) applies to only individuals who manufacture and distribute drugs ignores both the plain language of the statute and the remedial purpose of the Agency's debarment authority. Furthermore, Dr. DeLuca's argument that *Bhutani* v. *U.S. Food and Drug Administration,* 161 Fed. Appx. 589, 591 (7th Cir. 2006), and FDA's debarment order for Premchand Girdhari (65 FR 3454) evidence the court's and FDA's view that the statute is to be interpreted to exclude him is without merit. Both the court decision and FDA's debarment order address the specific fact situations at issue. Both situations involved persons who manufactured and distributed drugs. The decision and order did not purport to define the full scope of section 306(b)(2)(B)(i) of the FD&C Act or hold that conduct such as Dr. DeLuca's was not within the scope of the statutory provision.

Finally, Dr. DeLuca argues that FDA does not typically debar physicians for criminal violations of the FD&C Act. FDA has, however, debarred several other physicians under section 306(b)(2)(B)(i)(I) of the FD&C Act for convictions under the FD&C Act on the basis of similar conduct. (See, *e.g.,* 77 FR 27235, May 9, 2012; 76 FR 69272, November 8, 2011; 76 FR 30947, May 27, 2011; 76 FR 21910, April 19, 2011; 76 FR 13192, March 10, 2011; 76 FR 11789, March 3, 2011 (debarring physicians for felony violations of the FD&C Act for substituting TRI-toxin for BOTOX); 77 FR 27236, May 9, 2012; 76 FR 66072, October 25, 2011; 76 FR 48168, August 8, 2011; 76 FR 37126, June 24, 2011; 76 FR 30946, May 27, 2011; 76 FR 18556, April 4, 2011; 76 FR 18557, April 4, 2011; 76 FR 12971, March 9, 2011 (debarring physicians for a misdemeanor violations of the FD&C Act for substituting TRI-toxin for BOTOX).

Dr. DeLuca's arguments do not raise any genuine and substantial issue of fact for a hearing. Furthermore, Dr. DeLuca's legal arguments do not create a basis for a hearing and, in any event, are unpersuasive. Accordingly, the Chief Scientist denies Dr. DeLuca's request for a hearing.

As set forth in the proposal to debar and summarized in this document, Dr. DeLuca pled guilty to a misdemeanor under the FD&C Act for his role in offering a drug under the name of another. Based on the undisputed record before the Agency, the consideration in section 306(c)(3)(A) and (B) of the FD&C Act with respect to the nature and seriousness of the offense and extent in management participation involved are unfavorable in light of Dr. DeLuca's conduct in bringing the unapproved drug into the medical practice and his management position in The Plastic Surgery Group. At Dr. DeLuca's sentencing hearing, at which six other codefendants were also sentenced, the presiding judge in addressing Dr. DeLuca stated:

> And we're here because of your actions and inactions. As I said, your mistakes were different in kind and degree from those of your colleagues. It was you who brought this drug into the practice, and it was your conduct and your failure to check out either the company or the drug that you were ordering, as you should have done, your negligence in doing that that has brought us here today in the end.

Consistent with the proposal to debar, the record established that the medical practice of which Dr. DeLuca was a part ultimately took voluntary steps to mitigate the effect on the public health from its unlawful conduct and that Dr. DeLuca had no previous criminal convictions related to matters within FDA's jurisdictions. As such, the considerations in sections 306(c)(3)(C) and (F) of the FD&C Act will be treated as favorable factors.

In light of the totality of the circumstances underlying the foregoing four considerations, the seriousness of the offense and Dr. DeLuca's management participation make debarment for 5 years, consistent with the proposal to debar, appropriate in spite of the favorable factors under 306(c)(3)(C) and (F) of the FD&C Act.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under authority delegated to him by the Commissioner of Food and Drugs, finds: (1) That Dr. DeLuca has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the conduct underlying the conviction undermines the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Dr. DeLuca is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 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 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Dr. DeLuca, in any capacity during his period of debarment, will be subject to civil money penalties. If Dr. DeLuca, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application he will be subject to civil money penalties. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Dr. DeLuca during his period of debarment.

Any application by Dr. DeLuca for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2010–N–0303 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. Persons with access to the Internet may obtain documents in the Docket at *http://www.regulations.gov/.*

Dated: February 24, 2015.

Stephen Ostroff,

Director, Office of the Chief Scientist.

[FR Doc. 2015–05043 Filed 3–4–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0301]

Steven M. Lynch; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.