Botulinum Toxin Type A manufactured by [TRI] and known as 'TRI-toxin,' * * * in that [he] offered the ''TRI-toxin for sale by injection to patients under the name of another drug, [BOTOX].'' In short, Lentini pled guilty to, and was convicted of, misbranding a drug under the FD&C Act.

Section 306(a)(2) of the FD&C Act provides FDA with authority debar an individual who has been convicted of certain Federal felonies. The only relevant factual issue is whether Lentini was, in fact, convicted of a felony 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. Lentini does not dispute that he pled guilty to violating the requirements for drugs under the FD&C Act. Section 306(l) of the FD&C Act includes in its definition of a conviction, a guilty plea. Accordingly, Lentini's arguments regarding the factual circumstances underlying his plea fail to raise a genuine and substantial issue of fact as to whether he was convicted of a felony 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. Whether TRI also misbranded the drug is immaterial to the conduct underlying Lentini's conviction.

Lentini next argues that he entered the guilty plea underlying his felony conviction while under ''extreme duress'' and only because his attorneys advised him that the prosecution would ''find a way to convict him legally or illegally'' and that he should sign the plea agreement ''despite the facts.'' In Lentini's petition to enter a guilty plea in the criminal proceedings, however, he specifically attested that he was voluntarily agreeing to plead guilty because he was guilty of the offense underlying his conviction. He also stated in the petition that he had carefully reviewed every part of the agreement with his attorney and that the attorney counseled and advised him on the nature and elements of the charge to which he was pleading guilty, as well as any possible defenses. Under these circumstances, and in light of the court's acceptance of his guilty plea, Lentini's mere allegation that he was actually innocent of the offense and signed the plea agreement only at the urging of his attorney is insufficient to create a genuine and substantial issue of fact for resolution at a hearing. (See 21 CFR 12.24(b)(1)–(2)). Moreover, the FD&C Act does not permit consideration of factors such as the circumstances of an individual's guilty plea. As stated in this document, section 306(a)(2) the FD&C Act is clear that an individual shall be debarred upon a finding that he has been convicted of a felony 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. Lentini has been convicted of such a felony and is thus subject to debarment. If a court were to reverse Lentini's conviction on the ground that his plea was involuntary, or for any other reason, the order of debarment would be withdrawn pursuant to section 306(d)(3)(B)(i) of the FD&C Act.

III. Findings and Order

Therefore, the Chief Scientist and Deputy Commissioner for Science and Public Health, under section 306(a)(2) of the FD&C Act and under authority delegated to him, finds that Mr. Lentini has been convicted a of a felony 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.

As a result of the foregoing findings, Lentini is permanently debarred 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 May 9, 2012 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Lentini, in any capacity during his period of debarment, will be subject to civil money penalties. If Lentini, 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 Lentini during his period of debarment.

Any application by Lentini for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2010–N–0442 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: April 16, 2012.

Jesse L. Goodman,

Chief Scientist and Deputy Commissioner for Science and Public Health.

[FR Doc. 2012–11106 Filed 5–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0475]

Daphne I. Panagotacos; 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 Daphne I. Panagotacos and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Panagotacos 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 Panagotacos 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 Panagotacos's debarment, FDA has considered the relevant factors listed in the FD&C Act. Panagotacos 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 May 9, 2012.

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: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4210, Silver Spring, MD 20993, 301–796–4613.

SUPPLEMENTARY INFORMATION:

I. Background

On December 18, 2007, the United States District Court for the Central District of California entered judgment against Panagotacos, a physician, who pled guilty to a misdemeanor under the FD&C Act. Specifically, Panagotacos pled guilty to receiving in interstate commerce and delivering a misbranded drug in violation of sections 301(c), 502(f) and 303(a)(1) of the FD&C Act (21 U.S.C. 331(c), 352(f), 333(a)(1)). The basis for this conviction was conduct surrounding her injection of patients with TRI-toxin, an unapproved drug product purported to be botulinum toxin type A and distributed by Toxic Research International, Inc. (TRI), in Arizona. According to the records of the criminal proceedings, from January 2004 until November 2004, Panagotacos ordered 19 vials of TRI-toxin for her practice in California and used the TRI-toxin on herself, her employees, and her patients. As alleged in the criminal information to which she pled guilty, the TRI-toxin was misbranded in that it failed to bear adequate directions for use under section 502(f) of the FD&C Act.

Panagotacos 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 she 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 letters dated February 22, 2011, and March 14, 2011, FDA notified Panagotacos of a proposal to debar her for 5 years from providing services in any capacity to a person having an approved or pending drug product application. In a letter dated April 11, 2011, through counsel, Panagotacos requested a hearing on the proposal. In her request for a hearing, Panagotacos acknowledges the fact of her conviction under Federal law, as alleged by FDA. However, she argues that the conduct underlying her conviction does not warrant debarment.

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 and Deputy Commissioner for Science and Public Health has considered Panagotacos'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 her hearing request, Panagotacos first disputes the finding in the proposal to debar her that her misdemeanor conviction was based on conduct related to the regulation of drug products under the FD&C Act and that the conduct underlying her conviction undermined the process for the regulation of drugs. In support of this argument, Panagotacos asserts that her conviction under the FD&C Act was strict liability and that, based on assurances from TRI, she acted on the good faith belief that that TRI-toxin was a permissible generic form of BOTOX/BOTOX Cosmetic (BOTOX). As noted in this document, however, Panagotacos admitted, during her criminal proceedings, to receiving a misbranded drug in interstate commerce and delivering it to patients in violation of sections 301(c), 502(f) and 303(a)(1) of the FD&C Act.

Her conduct clearly related to the regulation of drug products under the FD&C Act because it was in direct violation of the FD&C Act's requirements for drug products. The conduct also undermined the process for the regulation of drugs in that it permitted an unapproved drug, TRI-toxin, to be administered to patients. With respect to Panagotacos's assertion that her offense was strict liability, section 306(b)(2)(B)(i) of the FD&C Act specifically provides for the debarment of individuals convicted of Federal misdemeanors related to the regulation of drug products under the FD&C Act. Given that a misdemeanor violation of the FD&C Act itself is a strict liability offense for which lack of criminal intent is no defense, criminal intent is not required to subject an individual to debarment under section 306(b)(2)(B)(i). Accordingly, Panagotacos is subject to debarment under section 306(b)(2)(B)(i).

Panagotacos next challenges the manner in which the proposal to debar applied the considerations under section 306(c)(3) of the FD&C Act in determining the appropriateness and period of her debarment. Section 306(c)(3) of the FD&C Act explicitly requires FDA to consider, ''where applicable,'' certain factors ''[i]n determining the appropriateness and the period of debarment'' for any permissive debarment. The proposal to debar Panagotacos set forth four applicable considerations under section 306(c)(3): (1) The nature and seriousness of her offense under section 306(c)(3)(A); (2) the nature and extent of management participation in the offense under section 306(c)(3)(B); (3) the nature and extent of voluntary steps taken to mitigate the impact on the public under section 306(c)(3)(C); and (4) prior convictions involving matters within the jurisdiction of FDA under section 306(c)(3)(F). In the proposal, FDA found that the first two considerations weigh in favor of debarring Panagotacos and noted that the third and fourth considerations would be treated as favorable factors for Panagotacos. In making all of its findings under section 306(c)(3), FDA relied on records from Panagotacos's criminal proceedings.

Panagotacos first challenges the finding in the proposal to debar her that the nature and seriousness of her offense, under section 306(c)(3)(A) of the FD&C Act, weigh in favor of debarment. She argues that ''[t]he nature and seriousness of the offense are in fact a favorable factor based on [her] diligent efforts to ascertain the truth and the plain evidence that she herself was a victim of fraud.'' Panagotacos's characterization of the conduct underlying her conviction is refuted by the criminal record. Her admissions during her criminal proceedings do not demonstrate that the nature and seriousness of her offense is a favorable factor because she made ''diligent efforts to ascertain the truth'' or because TRI made her a ''victim of fraud.''

The charge in the information to which Panagotacos pled guilty alleged that she ordered a misbranded drug from a source outside of her own state and used it on her patients. In a sentencing memorandum submitted to the criminal court on her behalf, Panagotacos also stated that she ''and her staff talked to representatives from TRI and were told that [TRI-toxin] was a safe generic form of [BOTOX] and that FDA approval was pending''. In the same sentencing memorandum, she also admitted to trying TRI-toxin on herself and on her staff and family to determine it was safe and effective before using it on patients. In a letter submitted in support of that memorandum, she further stated that ''the label on the bottle [of TRI-toxin] said that it was for research purposes only.'' In light of Panagotacos's admissions during her criminal proceedings that she knew TRI-toxin was an unapproved drug warranting further testing before she used it on her regular patients, the Chief Scientist and Deputy Commissioner for Science and Public Health finds, consistent with the proposal to debar, that the nature and seriousness of her offense weigh in favor of debarment. Panagotacos's mere assertion that TRI provided different information and convinced her that TRI-toxin was a

permissible generic form of BOTOX does not create a genuine and substantial issue of fact.

In her request for a hearing, Panagotacos further emphasizes that she not only stopped using TRI-toxin upon learning that TRI was being prosecuted for conduct related to its marketing of the drug product, she also took ''the extraordinary step'' of coming ''forward proactively to assist the investigation by providing information'' before she was contacted by investigators. Indeed, the criminal record discloses that she sent a letter to the prosecutor in which she stated that TRI had convinced her to purchase and use TRI-toxin on her patients but that she had stopped using the drug and was returning the product to TRI. She also offered in the letter to provide information to the prosecutor. In the Agency's proposal to debar, however, FDA took into account the circumstances Panagotacos now cites and considered her cooperation with government investigators as a favorable factor under section 306(c)(3)(C) of the FD&C Act. Therefore, her arguments affirming the circumstances and extent of her cooperation do not create a genuine and substantial issue of fact suitable for a hearing.

Panagotacos next challenges the manner in which FDA weighed the four factors that the Agency considered in the proposal to debar. She notes that, although FDA counted two of the four factors in her favor, it appears that the Agency did not take them into account because the proposal to debar found that she should be debarred for the maximum period of 5 years. Consistent with the proposal to debar, however, Panagotacos pled guilty to a misdemeanor under the FD&C Act for conduct related to her knowing purchase and use of an unapproved drug on her patients. She did so as a licensed physician with her own medical practice and thus held a position of authority relative to the offense of which she was convicted. The considerations in sections 306(c)(3)(A) and (B) of the FD&C Act weigh in favor of debarring Panagotacos for a maximum period of 5 years. Although the record establishes that Panagotacos took voluntary steps to mitigate the effect on the public health once she learned that there was a criminal investigation involving the company from which she purchased the unapproved drug (see section 306(c)(3)(C)), and although she appears to have no previous criminal convictions related to matters within the jurisdiction of FDA (see section 306(c)(3)(F)), these considerations do not counter to a sufficient degree the conduct underlying her misdemeanor conviction to warrant decreasing the period of debarment from 5 years.

III. Findings and Order

Therefore, the Chief Scientist and Deputy Commissioner for Science and Public Health, under section 306(b)(2)(B)(i) of the FD&C Act and under authority delegated to him, finds that Panagotacos 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 that the conduct underlying the conviction undermines the regulation of drugs. The Chief Scientist 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, Panagotacos 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 May 9, 2012 (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 Panagotacos, in any capacity during her period of debarment, will be subject to civil money penalties. If Panagotacos, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she 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 Panagotacos during her period of debarment.

Any application by Panagotacos for termination of debarment under section 306(d) of the FD&C Act should be identified with Docket No. FDA–2010–N–0475 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: April 16, 2012.

Jesse L. Goodman,

Chief Scientist and Deputy Commissioner for Science and Public Health.

[FR Doc. 2012–11112 Filed 5–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Pancreatic Beta Cell Function in women with PCOS.

Date: May 24, 2012.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Tracking Adolescents after Bariatric Surgery.

Date: May 25, 2012.

Time: 11:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases