ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002—(OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph (g) to section 704 of the Federal, Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program. FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.''

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C act/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
704(g) Request for Accreditation	1	1	1	80	80

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11179 Filed 5–8–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0442]

Jerome Lentini; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Jerome Lentini's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Lentini 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 Lentini 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. Lentini 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 11, 2006, the United States District Court for the District of Oregon entered a criminal judgment against Lentini pursuant to his guilty plea. Lentini, formerly a medical doctor at ''A Younger You'' clinic, pled guilty to a felony under the FD&C Act, namely misbranding a drug with an intent to defraud or mislead while it was held for sale after shipment in interstate commerce in violation of sections 301(k) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(k) and 333(a)(2)) and 18 U.S.C. 2. The basis for this conviction was Lentini's admission that he misled patients from November 2003 through December 2004, by injecting them with a drug product that he offered for sale as BOTOX/BOTOX Cosmetic (BOTOX). In fact, as defendant Lentini knew, he did not generally use BOTOX on patients but instead used another drug derived from botulinum toxin type A that had not been approved by FDA.

Lentini is subject to debarment based on a finding, under section 306(a)(2) of the FD&C Act (21 U.S.C. 335a(2)), that 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. By letter dated February 7, 2011, FDA notified Lentini of a proposal to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. In a letter dated February 19, 2011, Lentini requested a hearing on the proposal. In his request for a hearing, Lentini acknowledges his convictions under Federal law, as alleged by FDA, but he argues that he is actually innocent of the offense underlying his felony conviction.

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 Lentini'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 his request for a hearing, Lentini first argues that he did not misbrand the drug product at issue. Instead, he argues that the manufacturer of the drug product, Toxin Research International, Inc. (TRI), misbranded the product. As stated in the indictment in Lentini's criminal proceedings, however, a drug is misbranded under section 502(i)(3) of the FD&C Act (21 U.S.C. 352(i)(3)) if a drug ''is offered for sale under the name of another drug.'' The specific count to which Lentini pled guilty charged him with ''misbrand[ing] a drug, namely

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: