100 manufacturers and that approximately 12 hours will be spent on each label. The number of hours per label (response) is based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens. If an average of 12 hours is spent preparing, completing, and reviewing each of the estimated 3,600 sunscreen SKUs, the total number of hours dedicated to the one-time relabeling of currently marketed OTC sunscreen products, as necessary to comply with § 201.66 would be 43,200 (3,600 SKUs times 12 hours/SKU).

In addition to this one-time burden, we estimate that 60 new sunscreen SKUs marketed each year will have a third-party disclosure burden to comply with Drug Facts regulations equal to 720 hours annually (60 SKUs times 12 hours/SKU). We estimate that these new SKUs will be marketed by 20 manufacturers. We do not expect any OTC sunscreens to apply for exemptions or deferrals of the Drug Facts regulations in § 201.66(e).

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Format labeling in accordance with § 201.66(c) and (d) for existing sunscreen SKUs [2]	100	36	3,600	12	43,200
Format labeling in accordance with § 201.66(c) and (d) for new sunscreen SKUs [3]	20	3	60	12	720
Total first year burden					43,920
Total burden for each subsequent year					720

[1] FDA estimates a one-time medium capital cost of 6.1 million dollars will result from preparing labeling content and format for OTC sunscreens in accordance with § 201.66. There are no operating or maintenance costs associated with this collection of information.
[2] First-year burden for currently marketed OTC sunscreens.
[3] Burden for first and second years for currently marketed OTC sunscreens.

With the exception of the PDP statement of SPF value in § 201.327(a)(1), the labeling requirements in § 201.327(a) through (h), which provide other elements of the PDP, as well as specific content for indications, directions, and warnings, are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and, therefore, are not collections of information. These provisions are thus not subject to OMB review under the PRA.

Dated: May 3, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–11067 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–2012–N–0427]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Inspection by Accredited Persons Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002.

DATES: Submit either electronic or written comments on the collection of information by July 9, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4)

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