111.75(a)(1)(ii) sets forth the information a manufacturer is required to submit in such a petition. The regulation also contains a requirement to ensure that the manufacturer keeps our response to a petition submitted under § 111.75(a)(1)(ii) as a record under § 111.95. The collection of information in § 111.95 has been approved under OMB Control No. 0910–0606.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, importers, large businesses, and small businesses.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section; CGMP requirements for dietary supplements	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
111.75(a)(1)(ii)	1	1	1	8	8

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

In the last 3 years, we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients; therefore, the Agency estimates that one or fewer petitions will be submitted annually. Based on our experience with petition processes, we estimate it will take a requestor about 8 hours to prepare the factual and legal information necessary to support a petition for exemption and to prepare the petition. Although we have not received any new petitions to request an exemption from 100 percent identity testing of dietary ingredients in the last 3 years, we believe that OMB approval of these information collection provisions should be extended to provide for the potential future need of a firm in the dietary supplement industry to petition for an exemption from 100 percent identity testing of dietary ingredients.

Dated: November 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27222 Filed 11–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1393]

Agency Information Collection Activities; Proposed Collection; Comment Request; Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions

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 FDA's patent term restoration regulations on due diligence petitions for regulatory review period revision. Where a patented product must receive FDA approval before marketing is permitted, the Office of Patents and Trademarks may add a portion of the FDA review time to the term of a patent. Petitioners may request reductions in the regulatory review time if FDA marketing approval was not pursued with ''due diligence.''

DATES: Submit either electronic or written comments on the collection of information by January 13, 2014.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions—21 CFR Part 60 (OMB Control Number 0910–0233)—Extension

FDA's patent extension activities are conducted under the authority of the Drug Price Competition and Patent Term Restoration Act of 1984 (21 U.S.C. 355(j)) and the Generic Animal Drug and Patent Term Restoration Act of 1988 (35 U.S.C. 156). New human drug, animal drug, human biological, medical

device, food additive, or color additive products regulated by the FDA must undergo FDA safety, or safety and effectiveness, review before marketing is permitted. Where the product is covered by a patent, part of the patent's term may be consumed during this review, which diminishes the value of the patent. In enacting the Drug Price Competition and Patent Term Restoration Act of 1984 and the Generic Animal Drug and Patent Term Restoration Act of 1988, Congress sought to encourage development of new, safer, and more effective medical and food additive products. It did so by authorizing the U.S. Patent and Trademark Office (PTO) to extend the patent term by a portion of the time during which FDA's safety and effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with ''due diligence.''

The statute defines due diligence as ''that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.'' As provided in § 60.30(c), a due diligence petition ''shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.'' Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA's decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA's marketing permission for that product was not actively pursued throughout the regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 15 requests for revision of the regulatory review period have been submitted under § 60.24(a). For 2010, 2011, and 2012, a total of three requests have been submitted under § 60.24(a). During that same time period, there have been no requests under §§ 60.30 and 60.40; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
60.24(a)	1	1	1	100	100
60.30	1	1	1	50	50
60.40	1	1	1	10	10
Total	.....	.....	.....	.....	160

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

Dated: November 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–27226 Filed 11–13–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–N–0110]

Bruce I. Diamond; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Dr. Bruce I. Diamond's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Dr. Diamond for 10 years from providing services in any capacity to a person who has an approved or pending drug product application. FDA bases this order on findings that Dr. Diamond was convicted of felonies under State 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, was convicted of felonies involving fraud, and was a material participant in acts forming the basis of a conviction that subjects another person to debarment. In determining the appropriateness and length of Dr. Diamond's debarment period, FDA has evaluated the relevant considerations listed in the FD&C Act. Dr. Diamond has failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective November 14, 2013.

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., Silver Spring, MD 20993, 301–796–4613.

SUPPLEMENTARY INFORMATION:

I. Background

On December 16, 1997, Dr. Diamond pled guilty to 53 State criminal offenses, including felonies, in the Superior Court for the County of Richmond, Georgia, and the court subsequently entered judgment against him. The offenses in the Official Code of Georgia to which