Dated: October 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–26143 Filed 11–3–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0403]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. 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 invites comments on the information collection provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and the guidance entitled ''Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.''

DATES: Submit either electronic or written comments on the collection of information by January 5, 2015.

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 **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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Substantiation for Dietary Supplement Claims Made Under the Federal Food, Drug, and Cosmetic Act—21 U.S.C. 343(r)(6) (OMB Control Number 0910–0626)—Extension

Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. Under section 403(r)(6)(A) of the FD&C Act, such a statement is one that ''claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption for a nutrient or dietary ingredient.''

The guidance document, entitled ''Substantiation for Dietary Supplement Claims Made Under section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act,'' provides our recommendations to manufacturers about the amount, type, and quality of evidence they should have to substantiate a claim under section 403(r)(6) of the FD&C Act. The guidance does not discuss the types of claims that can be made concerning the effect of a dietary supplement on the structure or function of the body, nor does it discuss criteria to determine when a statement about a dietary supplement is a disease claim. The guidance document is intended to assist manufacturers in their efforts to comply with section 403(r)(6) of the FD&C Act. Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/FoodGuidances.*

Dietary supplement manufacturers collect the necessary substantiating information for their product as required by section 403(r)(6) of the FD&C Act. The guidance provides information to manufacturers to assist them in doing so. The recommendations contained in the guidance are voluntary. Dietary supplement manufacturers will only need to collect information to substantiate their product's nutritional deficiency, structure/function, or general well-being claim if they choose to place a claim on their product's label.

The standard discussed in the guidance for substantiation of a claim on the labeling of a dietary supplement is consistent with standards set by the Federal Trade Commission for dietary supplements and other health-related products that the claim be based on competent and reliable scientific evidence. This evidence standard is broad enough that some dietary supplement manufacturers may only need to collect peer-reviewed scientific journal articles to substantiate their claims; other dietary supplement manufacturers whose products have properties that are less well documented may have to conduct studies to build a body of evidence to support their claims. It is unlikely that a dietary supplement manufacturer will attempt to make a claim when the cost of obtaining the evidence to support the claim outweighs the benefits of having the claim on the product's label. It is likely that manufacturers will seek substantiation for their claims in the scientific literature.

The time it takes to assemble the necessary scientific information to support their claims depends on the product and the claimed benefits. If the product is one of several on the market making a particular claim for which

there is adequate publicly available and widely established evidence supporting the claim, then the time to gather supporting data will be minimal; if the product is the first of its kind to make a particular claim or the evidence supporting the claim is less publicly available or not widely established, then gathering the appropriate scientific evidence to substantiate the claim will be more time consuming.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Claim type	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Widely known, established	667	1	667	44	29,348
Pre-existing, not widely established	667	1	667	120	80,040
Novel	667	1	667	120	80,040
Total					189,428

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

We assume that it will take 44 hours to assemble information needed to substantiate a claim on a particular dietary supplement when the claim is widely known and established. We believe it will take closer to 120 hours to assemble supporting scientific information when the claim is novel or when the claim is pre-existing but the scientific underpinnings of the claim are not widely established. These are claims that may be based on emerging science, where conducting literature searches and understanding the literature takes time. It is also possible that references for claims made for some dietary ingredients or dietary supplements may primarily be found in foreign journals and in foreign languages or in the older, classical literature where it is not available on computerized literature databases or in the major scientific reference databases, such as the National Library of Medicine's literature database, all of which increases the time of obtaining substantiation.

In the **Federal Register** of January 6, 2000 (65 FR 1000), we published a final rule on statements made for dietary supplements concerning the effect of the product on the structure or function of the body. In that final rule, we estimated that there were 29,000 dietary supplement products marketed in the United States (65 FR 1000 at 1045). Assuming that the flow of new products is 10 percent per year, then 2,900 new dietary supplement products will come on the market each year. The structure/function final rule estimated that about 69 percent of dietary supplements have a claim on their labels, most probably a structure/function claim (65 FR 1000 at 1046). Therefore, we assume that supplement manufacturers will need time to assemble the evidence to substantiate each of the 2,001 claims ($2{,}900 \times 69$ percent) made each year. If we assume that the 2,001 claims are equally likely to be pre-existing widely established claims, novel claims, or pre-existing claims that are not widely established, then we can expect 667 of each of these types of claims to be substantiated per year. Table 1 of this document shows that the annual burden hours associated with assembling evidence for claims is 189,428 (the sum of 667×44 hours, 667×120 hours, and 667×120 hours).

Dated: October 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1698]

Food and Drug Administration Activities for Patient Participation in Medical Product Discussions; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; Establishment of docket; Request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket for comments on FDA activities performed under the Food and Drug Administration Safety and Innovation Act (FDASIA), Patient Participation in Medical Product Discussions. This notice announces FDA's intent to gather input from stakeholders on strategies to obtain the views of patients during the medical product development process and ways to consider patients' perspectives during regulatory discussions. This notice provides background on ongoing patient engagement activities, so that stakeholders can consider both current and new activities that involve patient participation and perspectives during medical product regulatory discussions.

DATES: Although FDA welcomes comments at any time, to help FDA address issues related to Patient Participation in Medical Products Discussions in a timely fashion, comments should be submitted by December 4, 2014.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Andrea Furia-Helms, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5319, Silver Spring, MD 20993–0002, *Andrea.Furia@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law FDASIA (Pub. L. 112–144). FDASIA expands the FDA's authorities and strengthens the Agency's ability to safeguard and advance public health in several areas including increasing stakeholder involvement in FDA regulatory processes. Specifically, section 1137 of FDASIA directs the Secretary of HHS to ''develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—(1) fostering participation of a patient representative who may serve as a special government employee in