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.

[FR Doc. 2014–26142 Filed 11–3–14; 8:45 am]

BILLING CODE 4164–01–P

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

appropriate agency meetings with medical product sponsors and investigators; and (2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.''

FDA has formed an Agency-wide working group to explore approaches and procedures as well as to align strategies across the Agency for patient participation in accordance with the statute. Involvement of the patient community brings the unique perspective of patients, family members, caregivers, and patient advocates to the decision-making processes of the FDA, and FDA is currently using a variety of tools to help ensure that the patient community is involved in medical product discussions to enhance benefit-risk assessment. FDA assesses the benefit-risk of new drugs and certain devices on a case-by-case basis. In this assessment, FDA may consider, among other things, the degree of unmet medical need and the severity and morbidity of the condition or disease the drug or device is intended to treat or diagnose. This approach has been critical to increasing patient access to new treatments for cancer, other serious diseases, and rare diseases, where existing therapies have been few and limited in their effectiveness.

Currently, patient representatives can serve as Special Government Employees (SGEs) in order to participate as a member of an FDA's federal advisory committee meeting about medical products undergoing the FDA review process for marketing approval and other regulatory issues. Patient representatives serve as committee members on advisory committees managed by the Office of the Commissioner, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health. SGE patient representatives may also serve on special assignments to provide feedback and perspective on product reviews in progress. These SGE activities are in addition to the many other activities in which FDA obtains patient perspectives, such as open public hearings on specific diseases or drug development issues, and as speakers at FDA-sponsored conferences and workshops.

FDASIA includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biological products. This is the fifth authorization of PDUFA (otherwise known as ''PDUFA V''), which was, as directed by Congress, developed in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. Under PDUFA V, FDA intends to conduct at least 20 public meetings that aim to more systematically gather patients' perspectives on their conditions and available therapies to treat those conditions (Patient Focused Drug Development). PDUFA V also includes an initiative to enhance FDA's review of patient-reported outcome study endpoints and endpoint assessment tools.

FDASIA also includes the reauthorization of the Medical Device User Fee Act (MDUFA) that provides FDA the necessary resources to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market. This third authorization of MDUFA (otherwise known as ''MDUFA III''), was a result of more than a year of public input, negotiations with industry representatives, and discussions with patient and consumer stakeholders. Under MDUFA III, FDA has established the Patient Preference Initiative to provide the information, guidance, and framework necessary to incorporate patient preferences on the benefit-risk tradeoffs of medical devices into the full spectrum of medical device regulatory processes and to inform medical device innovation by the larger medical device community. In the process, the initiative aims to advance the science of measuring medical device preferences of patients, caregivers, and providers. Once the Patient Preference Initiative helps to define or refine the methods to measure patient preferences, FDA intends to incorporate patient views into the total product life cycle of medical devices.

FDA is opening a docket for 30 days to provide an opportunity for interested stakeholders to submit comments on ''strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions'' under section 1137 of FDASIA. FDA is interested in comments on both current and new activities that would involve patient participation in regulatory discussions, as well as comments on ways to assess patient participation activities.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

Dated: October 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.