TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Recall	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm Initiated Recall (21 CFR 7.46) and Recall Communications (21 CFR 7.49)	3,801	1	3,801	25	95,025
Recall Status Reports (21 CFR 7.53)	3,801	13	49,413	10	494,130
Termination of a Recall (21 CFR 7.55(b))	3,801	1	3,801	10	38,010
Total					627,165

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

I. Total Annual Reporting

A. Firm Initiated Recall and Recall Communications

Request firms voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA District Office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 3,801 responses annually based on the average number of recalls over the last 3 fiscal years. The number of responses multiplied by the number of respondents equal 3,801. The average burden hours of 25 multiplied by the total number of annual responses equal 95,025. The average burden hour person response was 30 and has decreased by 5.

B. Recall Status Reports

Request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and is estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 3,801 responses annually, based on the average number of recalls over the last 3 fiscal years (11,403). The number of respondents multiplied by the number of responses per respondents (13) equal a total number of annual responses of 49,413. The total number of responses 49,413 with an average burden hours of 10 per response equal a total of 494,130 total hours.

C. Termination of a Recall

Provide the firms an opportunity to request in writing that FDA end the recall. The Agency estimates it will receive 3,801 responses annually based on the average number of terminations over the past 3 fiscal years. The total annual responses of 3,801 multiplied by the average burden hours of 10 per response equal a total number of hours of 38,010.

II. Total Annual Third-Party Disclosure Burden

Recall Communications. Request firms to notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under this portion of the collection of information, the Agency estimates firms will provide 1,691,445 notifications annually based on the number of respondents/consignees (3,807) multiplied by the number of disclosures per respondent (445). The total number of hours is 94,721 (based on 1,691,445 multiplied by 0.056 hours).

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

21 CFR Part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall Communications (21 CFR 7.49)	3,801	445	1,691,445	0.056 (3 minutes)	94,721

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all third-party disclosures provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. FDA estimates the burden for third-party disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall (445) results in a burden per disclosure estimate of approximate hours (25 hours per recall/445 disclosures/recall = 0.056 hours).

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–02788 Filed 2–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 13, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0626. Also include the FDA 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, 8455 Colesville Road; COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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.

In the **Federal Register** of November 4, 2014 (79 FR 65409), FDA published a 60-day notice requesting public comment on the proposed collection of information. Five comments were received. One comment agreed with the Agency's burden estimate while the remaining comments were not responsive to four information collection topics solicited in the notice and are therefore not discussed in this document.

FDA estimates 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: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0630]

Safety Considerations To Mitigate the Risks of Misconnections With Small-Bore Connectors Intended for Enteral Applications; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Safety Considerations to Mitigate the Risks of Misconnections with Small-Bore Connectors Intended for Enteral Applications.'' The use of common connector designs, such as Luer connectors, has led to unintended connections between devices that have different intended uses and has resulted in serious and sometimes fatal consequences to patients. This guidance provides recommendations to manufacturers regarding the expectations for design and testing of small-bore connectors intended for enteral applications (''enteral devices''). FDA is making these recommendations to reduce the risk of unintended connections between enteral and non-enteral devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Safety Considerations to Mitigate the Risks of Misconnections with Small-Bore Connectors Intended for Enteral Applications'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance 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. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Priya Venkataraman-Rao, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G222, Silver Spring, MD 20993–0002, 301–796–6243.

SUPPLEMENTARY INFORMATION:

I. Background

Numerous publications regarding patient injury and death from tubing and catheter misconnections indicate that reports of misconnections have increased in frequency over the past several years. On July 9, 2010, FDA issued a letter to healthcare professionals, hospital purchasing departments, and manufacturers of enteral feeding tubes regarding Luer lock misconnections (Ref. 1). FDA advised manufacturers to assess the risks of misconnections for their devices and provide proposed solutions with validation for premarket review. At that time, some manufacturers were using color-coding and labeling to reduce the risk of misconnections; others were creating proprietary connectors designed to be incompatible with devices for non-enteral applications (''non-enteral devices''). However, recent reports of adverse events have demonstrated that reliance on color-coding and tagging of enteral devices alone cannot adequately mitigate the risk of misconnections, especially with similarly color-coded intravenous PICC (percutaneously inserted central catheter) lines with Luer connectors.

This guidance provides updated recommendations to manufacturers of small-bore connectors intended for enteral applications. The guidance recommends that manufacturers: (1) Design and test enteral connectors based upon Association for the Advancement of Medical Instrumentation (AAMI)/CN3:2014 (PS), ''Small-bore connectors for liquids and gases in healthcare applications—Part 3: Connectors for enteral applications'' and AAMI/CN20:2014 (PS), ''Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods''; (2) for connectors that do not meet AAMI/CN3:2014 (PS), design and test connectors based upon the AAMI/American National Standards Institute (ANSI)/International Organization for Standardization (ISO) 80369–1 standard ''Small-bore connectors for liquids and gases in healthcare applications—Part 1: