from 3,000 adult members in online consumer panels maintained by a contractor. The study plans to randomly select 800 panel members in each of three groups: Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics. Both English and Spanish questionnaires will be used, as appropriate. The study plans to include topics such as: (1) Food safety knowledge and attitude and (2) food handling and consumption practice. To help us understand the data, the study will also collect information on respondents' background, including, but not limited to, health status and demographic characteristics, such as age, gender, education, and income, and degree of acculturation among Hispanic respondents using a measure developed by Marin, et al. (Ref. 6).

The study is part of our continuing effort to protect the public health. We will not use the results of the study to develop population estimates. We will use the results of the study to develop followup quantitative and qualitative research to gauge the prevalence and extent of differences in food safety knowledge and behaviors between the three mentioned population groups. We will use the results of the followup research to help inform the design of effective education and outreach initiatives aimed at helping reduce the risk of foodborne illness for the general U.S. population as well as Hispanics.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener	72	1	72	0.083 (5 minutes)	6
Cognitive interview	9	1	9	0.5 (30 minutes)	5
Pretest invitation	1,440	1	1,440	0.033 (2 minutes)	48
Pretest	180	1	180	0.25 (15 minutes)	45
Study invitation	24,000	1	24,000	0.033 (2 minutes)	792
Study	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,646

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

We base our estimates on prior experience with research that is similar to this proposed study. We will use a cognitive interview screener with 72 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 5.976 hours, rounded to 6 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 30 minutes to complete the interview, for a total of 4.5 hours, rounded to 5 hours. We also plan to conduct a pretest to identify and resolve potential survey administration problems. We will send a pretest invitation to 1,440 prospective pretest participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 47.52 hours, rounded to 48 hours. We will administer the pretest with 180 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 45 hours. We will send a study invitation to 24,000 prospective participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 792 hours. We will administer the study with 3,000 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the study, for a total of 750 hours. The total estimated burden for all the study activities is 1,646 hours.

II. References

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Dated: November 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1152]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 December 29, 2014.

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 0910–0608. 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 Rd.; 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.

Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients:

Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements—21 CFR 111.75(a)(1)(ii) (OMB Control Number 0910–0608)—Reinstatement

The Dietary Supplement Health and Education Act (DSHEA) (Pub. L. 103–417) added section 402(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(g)), which provides, in part, that the Secretary of Health and Human Services (the Secretary) may, by regulation, prescribe good manufacturing practices for dietary supplements. Section 402(g)(1) of the FD&C Act states that a dietary supplement is adulterated if ''it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.'' Section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives us the authority to issue regulations for the efficient enforcement of the FD&C Act.

Part 111 of our regulations (21 CFR part 111) establishes the minimum current good manufacturing practice (CGMP) necessary for activities related to manufacturing, packaging, labeling, or holding dietary supplements to ensure the quality of the dietary supplement. Section 111.75(a)(1) of our regulations establishes a procedure for a petition to request an exemption from 100 percent identity testing of dietary ingredients. In accordance with § 111.75(a)(1)(ii), manufacturers may request an exemption from the requirements set forth in § 111.75(a)(1)(i) when the dietary ingredient is obtained from one or more suppliers identified in the petition. The regulation clarifies that we are willing to consider, on a case-by-case basis, a manufacturer's conclusion, supported by appropriate data and information in the petition submission, that it has developed a system that it would implement as a sound, consistent means of establishing, with no material diminution of assurance compared to the assurance provided by 100 percent identity testing, the identity of the dietary ingredient before use.

Section 111.75(a)(1) reflects our determination that manufacturers that test or examine 100 percent of the incoming dietary ingredients for identity can be assured of the identity of the ingredient. However, we recognize that it may be possible for a manufacturer to demonstrate, through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing. To provide an opportunity for a manufacturer to make such a showing and reduce the frequency of identity testing of components that are dietary ingredients from 100 percent to some lower frequency, we added to § 111.75(a)(1), an exemption from the requirement of 100 percent identity testing when a manufacturer petitions the Agency for such an exemption to 100 percent identity testing under § 10.30 and the Agency grants such exemption. Such a procedure would be consistent with our stated goal, as described in the CGMP final rule, of providing flexibility in the CGMP requirements. Section 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 number 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.

In the **Federal Register** of November 14, 2013 (78 FR 68453), FDA published a 60-day notice requesting public comment on the proposed collection of information. While three comments were received, none were responsive to the four collection of information topics solicited in the notice and therefore are not discussed in this document. Additionally, although FDA was unable to publish a 30 day notice before the information collection expiration and is therefore requesting its reinstatement, the Agency has not conducted or sponsored any collection of information under OMB control number 0910–0608 in the interim period.

We estimate the annual 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 21, 2014.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1981]

The Drug Supply Chain Security Act Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How To Exchange Product Tracing Information.'' The draft guidance addresses the drug supply chain security provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which requires the Secretary of the Department of Health and Human Services to establish initial standards for the interoperable exchange of transaction information, transaction history, and transaction statements, in paper or electronic format. Specifically, the guidance establishes standards for how transaction information, transaction history, and transaction statements should be exchanged among trading partners through the extension and/or use of current systems and processes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by January 27, 2015. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by January 27, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3100, *drugtrackandtrace@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, the Drug Supply Chain Security Act (Title II of Public Law 113–54) was signed into law. Section 202 of the Drug Supply Chain Security Act (DSCSA), which adds new sections 581 and 582 to the FD&C Act (21 U.S.C. 360eee and 360eee–1), sets forth new definitions and requirements related to product tracing. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States.

Starting in 2015, certain trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) are required under sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to capture, maintain, and provide the subsequent purchaser with transaction information, transaction history, and a transaction statement (product tracing information) for certain prescription drug products. Manufacturers, wholesale distributors, and repackagers must meet these requirements by January 1, 2015; dispensers must meet them by July 1, 2015. In addition, each manufacturer, wholesale distributor, dispenser, and repackager must comply with all applicable requirements in the event they meet the definition of more than one trading partner under section 582(a)(1), but trading partners are not required to duplicate requirements. Section 582(a)(2)(A) of the FD&C Act directs FDA to establish initial standards to facilitate the interoperable exchange of transaction information, transaction history, and transaction statements between trading partners.

FDA obtained stakeholder input on the development of the initial standards for the interoperable exchange of product tracing information, in paper and electronic formats, through a public docket established in February 2014, as required under section 582(a)(2)(B), and a public workshop that was held May 8 and 9, 2014. The public workshop provided a forum for FDA to obtain input from stakeholders in the pharmaceutical distribution supply chain on how trading partners can best comply with the requirements for the interoperable exchange of product tracing information beginning in 2015, using currently available standards or practices. Comments to the public dockets and from the workshop were considered in the development of this guidance, and will be considered in developing additional guidance to further elaborate on the standards for the interoperable exchange of product tracing information.

This initial draft guidance establishes standards to help trading partners comply with the requirements of sections 582(b)(1), (c)(1), (d)(1), and (e)(1) of the FD&C Act to provide the subsequent trading partners with product tracing information, in paper or electronic format, through the extension and/or use of current systems and processes. Under these provisions, trading partners are also required to capture and maintain the applicable product tracing information for not less than 6 years after the date of the transaction. Implementation of these provisions will help further improve the security of the pharmaceutical distribution supply chain and increase confidence in the safety and authenticity of human prescription drugs. FDA intends to issue additional guidance to facilitate the interoperable exchange of product tracing information through standardization of data and documentation practices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is marked as a ''draft'' consistent with its description in section 582(a)(2)(A) of the FD&C Act.