SUPPLEMENTARY INFORMATION: On June 18, 2014, the Agency submitted a proposed collection of information entitled ''Testing Communications on Biological Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0687. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21533 Filed 9–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0920]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Health and Diet Survey

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 October 10, 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 0910–0545. 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.

Health and Diet Survey as Used by the Food and Drug Administration—(OMB Control Number 0910–0545)—(Revision)

We are seeking OMB approval to revise the Health and Diet Survey, which is a voluntary consumer survey intended to gauge and to track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. Currently this collection is approved as a traditional collection; however, the Agency wishes to employ future collections under the generic collection process. The authority for FDA to collect the information derives from FDA's Commissioner of Food and Drugs authority provided in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

We will use the Health and Diet Survey findings to test and refine our ideas, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

This survey has been repeated approximately every 3 to 5 years over the course of the past 3 decades for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified in each iteration in response to emerging and current events or issues. In the next 3 years, we plan to field the survey two to three times. We will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy diets and lifestyles. The information will also help FDA evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 States and the District of Columbia. Participation will be voluntary.

In the **Federal Register** of July 14, 2014 (79 FR 40760), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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	100	1	100	0.083 (5 minutes)	8
Cognitive interview	18	1	18	1	18
Pretest screener	2,000	1	2,000	0.033 (2 minutes)	66
Pretest	200	1	200	0.25 (15 minutes)	50
Survey screener	30,000	1	30,000	0.033 (2 minutes)	990
Survey	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,882

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

We base our estimate of the number of respondents and the average burden per response on our experience with previous Health and Diet Surveys. We will use a cognitive interview screener with 100 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 8 hours, rounded down from 8.3 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take a participant approximately 1 hour

to complete the interview, for a total of 18 hours. Prior to the administration of the Health and Diet Survey, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. We will use a pretest screener with 2,000 individuals; we estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the pretest screener, for a total of 66 hours. The pretest will be conducted with 200 participants; we estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 50 hours. We will use a survey screener to select an eligible adult respondent in each household reached by landline telephone numbers to participate in the survey. A total of 30,000 individuals in the 50 states and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 2 minutes (0.033 hours) to complete the screening, for a total of 990 hours. We estimate that 3,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 750 hours. Thus, the total estimated burden is 1,882 hours.

We are requesting this burden for unplanned surveys so as not to restrict our ability to gather information on consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. This ability will help the Agency identify and respond to emerging issues in a more timely manner.

Dated: September 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21532 Filed 9–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1182]

Unique Device Identification System: Small Entity Compliance Guide; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Unique Device Identification System: Small Entity Compliance Guide'' for a final rule published in the **Federal Register** of September 2013. This small entity compliance guide (SECG) intends to provide, in plain language, the requirements of the regulation and to help small businesses understand and comply with the regulation.

DATES: Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit written requests for single copies of the SECG entitled ''Unique Device Identification System: Small Entity Compliance Guide'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests.

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: For CDRH questions regarding this document, contact UDI Regulatory Policy Support, 301–796–5995, email: *udi@fda.hhs.gov*. For CBER questions regarding this document, contact Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled: ''Unique Device Identification System: Small Entity Compliance Guide.''

Section 226 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) and section 614 of the Food and Drug Administration Safety and Innovation Act (Pub. L.112–144) amended the Federal Food, Drug, and Cosmetic Act to add section 519(f) (21 U.S.C. 360i(f)), which directs FDA to issue regulations establishing a unique device identification system for medical devices.

In the **Federal Register** of September 24, 2013 (78 FR 58785), FDA published a final rule establishing a unique device identification system (the UDI Rule). Some parts of the rule became effective on October 24, 2013; the remaining parts became effective on December 23, 2013. In addition, certain provisions within the rule have later compliance dates. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), FDA is making available this SECG stating in plain language the legal requirements of the September 24, 2013, final rule.

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 and 830 have been approved under OMB control number 0910–0720; the collections of information in part 803 have been approved under OMB control number 0910–0437; the collections of information in part 806 have been approved under OMB control number 0910–0359; the collections of information in part 810 have been approved under OMB control number 0910–0432; the collections of information in part 814 have been approved under 0910–0231; the collections of information in part 821 have been approved under OMB control number 0910–0442; and the collections of information in part 822 have been approved under OMB control number 0910–0449.

III. 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