TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
120.6(c) and 120.12(a)(1) and (b)—Require written monitoring and correction records for Sanitation Standard Operating Procedures.	1,875	365	684,375	0.1 (6 minutes)	68,438
120.7, 120.10(a), and 120.12(a)(2), (b) and (c)—Require written hazard analysis of food hazards.	2,300	1.1	2,530	20	50,600
120.8(a) and 20.12(a)(3), (b), and (c)—Require written HACCP plan	1,560	1.1	1716	60	102,960
120.8(b)(7) and 120.12(a)(4)(i) and (b)—Require a recordkeeping system that documents monitoring of the critical control points and other measurements as prescribed in the HACCP plan.	1,450	14,600	21,170,000	0.01 (1 minute)	211,700
120.10(c) and 120.12(a)(4)(ii) and (b)—Require that all corrective actions taken in response to a deviation from a critical limit be documented.	1,840	12	22,080	0.1 (6 minutes)	2,208
120.11(a)(1)(iv) and (a)(2) and 120.12 (a)(5) and (b)—Require records showing verification activities associated with the HACCP system.	1,840	52	95,680	0.1 (6 minutes)	9,568
120.11(b) and 120.12(a)(5) and (b)—Require records showing validation activities associated with the HACCP system.	1,840	1	1,840	4	7,360
120.11(c) and 120.12(a)(5) and (b)—Require documentation of revalidation of the hazard analysis upon any changes that might affect the original hazard analysis (applies when a firm does not have a HACCP plan because the original hazard analysis did not reveal hazards likely to occur).	1,840	1	1,840	4	7,360
120.14(a)(2), (c), and (d) and 120.12(b)—Require that juice importers have written procedures to ensure that the juice is processed in accordance with our regulations in part 120.	308	1	308	4	1,232
Total					461,426

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

Table 1 provides our estimate of the total annual recordkeeping burden of our regulations in part 120. We base our estimate of the average burden per recordkeeping on our experience with the application of HACCP principles in food processing. We base our estimate of the number of recordkeepers on our estimate of the total number of juice manufacturing plants affected by the regulations (plants identified in our official establishment inventory plus very small apple juice and very small orange juice manufacturers). These estimates assume that every processor will prepare sanitary standard operating procedures and an HACCP plan and maintain the associated monitoring records, and that every importer will require product safety specifications. In fact, there are likely to be some small number of juice processors that, based upon their hazard analysis, determine that they are not required to have an HACCP plan under these regulations.

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05105 Filed 3–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0796]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting Products

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 April 14, 2017.

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 0910–0678. 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, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Testing Communications on Medical Devices and Radiation-Emitting Products—OMB Control Number 0910–0678—Extension

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation emitting products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about medical device and radiation-emitting product use. Knowledge of consumer and health care professional decision making processes

will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

Annually, FDA projects about 30 studies using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08 to 1.5 hours). FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of October 28, 2016 (81 FR 75134), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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
Individual in-depth interviews	360	1	360	.75 (45 minutes)	270
General public focus group interviews	144	1	144	1.5	216
Intercept interviews: Central location	200	1	200	.25 (15 minutes)	50
Intercept interviews: Telephone	4,000	1	4,000	.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	.5 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	.17 (10 minutes)	204
Total (general public)	8,704				1,860
Physician focus group interviews	144	1	144	1.5	216
Total (physician)	144				216
Total (overall)	8,848				2,076

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

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–05097 Filed 3–14–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1089]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

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 April 14, 2017.

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 0910–0553. 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, Three White Flint North 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Recommended Glossary and Educational Outreach To Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

OMB Control Number 0910–0553—Extension

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device to avoid misbranding. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.