

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Second postcard	60	1	60	.03 (2 min.)	2
Survey	35	1	35	.33 (20 min.)	12
Main Study					
Survey invitation letter	5,042	1	5,042	.08 (5 min.)	403
Reminder postcard	5,042	1	5,042	.03 (2 min.)	151
Non-response letter	4,173	1	4,173	.08 (5 min.)	334
Non-response questionnaire letter	4,073	1	4,073	.08 (5 min.)	326
Second postcard	3,063	1	3,063	.03 (2 min.)	92
Survey	1,765	1	1,765	.33 (20 min.)	582
Total					1927

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

II. References

The following references are on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. Aikin, K.J., J.L. Swasy, and A.C. Braman, "Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results," 2004. (<http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/ucm152860.pdf>).

2. PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines 2008. (<http://phrma.org/sites/default/files/pdf/phrmaguidingprinciplesdec08final.pdf>).

3. Dillman, D.A., J.D. Smyth, and L.M. Christian, *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method*, 4th ed. Hoboken, NJ: John Wiley & Sons, Inc., 2014.

4. American Association for Public Opinion Research, "Address-based Sampling," 2016. (http://www.aapor.org/AAPOR_Main/media/MainSiteFiles/AAPOR_Report_1_7_16_CLEAN-COPY-FINAL.pdf).

5. Millar, M.M. and D.A. Dillman, "Improving Response to Web and Mixed-Mode Surveys," *Public Opinion Quarterly* 1–21. 2011.

6. Shaw, M.J., T.J. Beebe, H.L. Jensen, and S.A. Adlis, "The Use of Monetary Incentives in a Community Survey: Impact on Response Rates, Data Quality, and Cost," *Health Services Research* 35:1339–1346. 2011.

7. Montaquila, J.M., J.M. Brick, D. Williams, K. Kim, et al., "A Study of Two-Phase Mail Survey Data Collection Methods,"

Journal of Survey Statistics and Methodology 1(1), 66–87. 2013.

Dated: July 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2012–N–1210; FDA–2004–N–0258]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food Labeling: Nutrition Facts and Supplement Facts Label and Reference Amounts Customarily Consumed per Eating Occasion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Food Labeling: Nutrition Facts and Supplement Facts Label and Reference Amounts Customarily Consumed Per Eating Occasion" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: On May 27, 2016, the Agency submitted a proposed collection of information entitled "Food Labeling: Nutrition Facts

and Supplement Facts Label and Reference Amounts Customarily Consumed Per Eating Occasion" 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 0910–0813. The approval expires on July 31, 2019. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: August 1, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2016–M–1122, FDA–2016–M–1123, FDA–2016–M–1124, FDA–2016–M–1125, FDA–2016–M–1165, FDA–2016–M–1166, FDA–2016–M–1167, FDA–2016–M–1168, FDA–2016–M–1222, FDA–2016–M–1223, FDA–2016–M–1400, FDA–2016–M–1401, FDA–2016–M–1455, FDA–2016–M–1459, FDA–2016–M–1754, and FDA–2016–M–1755]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications