

- Quantitative Review," *PLoS One*, 5(3):e9434, 2010.
31. Ascherio, A., M. B. Katan, P. L. Zock, et al., "Trans Fatty Acids and Coronary Heart Disease," *New England Journal of Medicine*, 340:1994–1998, 1999.
 32. Zock, P. L., M. B. Katan, and R. P. Mensink, "Dietary Trans Fatty Acids and Lipoprotein Cholesterol" [Letter to the editor], *American Journal of Clinical Nutrition*, 61:617, 1995.
 33. Mensink, R. P., P. L. Zock, A. D. Kester, et al., "Effects of Dietary Fatty Acids and Carbohydrates on the Ratio of Serum Total to HDL Cholesterol and on Serum Lipids and Apolipoproteins: A Meta-Analysis of 60 Controlled Trials," *American Journal of Clinical Nutrition*, 77:1146–1155, 2003.
 34. Mozaffarian, D., M. B., Katan, A. Asherio, et al., "Trans Fatty Acids and Cardiovascular Disease," *New England Journal of Medicine*, 354:1601–1613, 2006.
 35. Dourson, M. "Mode of Action and Dose-Response Evaluation of the Effect of Partially Hydrogenated Oils on LDL-Cholesterol," Presented at the SOT FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety, November 7, 2014.
 36. National Research Council, *Science and Decisions: Advancing Risk Assessment*, National Academies Press, Washington, DC, 2009; <http://www.nap.edu>.
 37. Keys, A., J. T. Anderson, F. Grande, "Serum Cholesterol Response to Changes in the Diet: I. Iodine Value of Dietary Fat Versus 2S-P," *Metabolism*, 14:747–758, 1965.
 38. Hegsted, D. M., R. B. McGandy, M. L. Myers, et al., "Quantitative Effects of Dietary Fat on Serum Cholesterol in Man," *American Journal of Clinical Nutrition*, 17:281–295, 1965.
 39. Keys, A. and R. W. Parlin, "Serum Cholesterol Response to Changes in Dietary Lipids," *American Journal of Clinical Nutrition*, 19:175–181, 1966.
 40. Page, I. H., E. V. Allen, F. L. Chamberlain, et al., "Dietary Fat and Its Relation to Heart Attacks and Strokes," *Circulation*, 23:133–136, 1961.
 41. Clarke, R., C. Frost, R. Collins, et al. "Dietary Lipids and Blood Cholesterol: Quantitative Meta-Analysis of Metabolic Ward Studies," *BMJ*, 314:112–117, 1997.
 42. Mensink R. P. and M. B. Katan, "Effect of Dietary Fatty Acids on Serum Lipids and Lipoproteins. A Meta-Analysis of 27 Trials," *Arteriosclerosis, Thrombosis, and Vascular Biology*, 12:911–919, 1992.
 43. Reeves, R. M., "Effect of Dietary Trans Fatty Acids on Cholesterol Levels" [Letter to the editor], *New England Journal of Medicine*, 324:338–339, 1991.
 44. Katan M. B., P. L. Zock, R. P. Mensink, "Trans Fatty Acids and their Effects on Lipoproteins in Humans," *Annual Review of Nutrition*, 15:473–493, 1995.
 45. Zock P. L. and R. P. Mensink, "Dietary Trans-Fatty Acids and Serum Lipoproteins in Humans," *Current Opinion in Lipidology*, 7:34–37, 1996.
 46. Oh, K., F. B. Hu, J. E. Manson, et al., "Dietary Fat Intake and Risk of Coronary Heart Disease in Women: 20 Years of Follow-up of the Nurses' Health Study," *American Journal of Epidemiology*, 161:672–679, 2005.
 47. Ascherio A., E. B. Rimm, E. L. Giovannucci, et al., "Dietary Fat and Risk of Coronary Heart Disease in Men: Cohort Follow Up Study in the United States," *BMJ*, 313:84–90, 1996.
 48. Willett W. C., M. J. Stampfer, J. E. Manson, et al., "Intake of Trans Fatty Acids and Risk of Coronary Heart Disease Among Women," *Lancet*, 341:581–585, 1993.
 49. Hu, F. B., M. J. Stampfer, J. E. Manson, et al., "Dietary Fat Intake and the Risk of Coronary Heart Disease in Women," *New England Journal of Medicine*, 337:1491–1499, 1997.
 50. Pietinen, P., A. Ascherio, P. Korhonen, et al., "Intake of Fatty Acids and Risk of Coronary Heart Disease in a Cohort of Finnish Men. The Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study," *American Journal of Epidemiology*, 145:876–887, 1997.
 51. Oomen, C. M., M. C. Ocke, E. J. Feskens, et al., "Association Between Trans Fatty Acid Intake and 10-year Risk of Coronary Heart Disease in the Zutphen Elderly Study: A Prospective Population-Based Study," *Lancet*, 357:746–751, 2001.
 52. Mozaffarian D., A. Aro, W. C. Willett, "Health Effects of Trans-fatty Acids: Experimental and Observational Evidence," *European Journal of Clinical Nutrition*, 63:S5–21, 2009.
 53. Skeaff C. M. and J. Miller, "Dietary Fat and Coronary Heart Disease: Summary of Evidence from Prospective Cohort and Randomised Controlled Trials," *Annals of Nutrition & Metabolism*, 55:173–201, 2009.
 54. Bendtsen N. T., R. Christensen, E. M. Bartels, et al., "Consumption of Industrial and Ruminant Trans Fatty Acids and Risk of Coronary Heart Disease: A Systematic Review and Meta-analysis of Cohort Studies," *European Journal of Clinical Nutrition*, 65:773–783, 2011.
 55. Chowdhury R., S. Warnakula, S. Kunutsor, et al., "Association of Dietary, Circulating, and Supplement Fatty Acids with Coronary Risk. A Systematic Review and Meta-analysis," *Annals of Internal Medicine*, 160:398–406, 2014.
 56. Trumbo, P. R. and T. Shimakawa, "Tolerable Upper Intake Levels for Trans Fat, Saturated Fat, and Cholesterol," *Nutrition Reviews*, 69:270–278, 2011.
 57. Willett W. C., "Dietary Fats and Coronary Heart Disease," *Journal of Internal Medicine*, 272:13–24, 2012.
 58. National Heart, Lung, and Blood Institute, "Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review From the Lifestyle Work Group," Bethesda, MD: HHS, National Institutes of Health, 2013 (<http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/lifestyle>).
 59. Burlingame B., C. Nishida, R. Uauy, et al., "Fats and Fatty Acids in Human Nutrition: Introduction," *Annals of Nutrition & Metabolism*, 55:5–7, 2009.
 60. Uauy, R., A. Aro, R. Clarke, et al., "WHO Scientific Update on Trans Fatty Acids: Summary and Conclusions," *European Journal of Clinical Nutrition*, 63: S68–S75, 2009.
 61. Food and Agricultural Organization of the United Nations (FAO) and WHO, *Fats and Fatty Acids in Human Nutrition. Report of an Expert Consultation*. Rome: FAO; 2010.
 62. Eckel, R. H., J. M. Jakicic, J. D. Ard, et al. "2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines," *Circulation*, 129:S76–S99, 2014.
 63. European Food Safety Authority (EFSA), "Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a Request from the Commission Related to the Presence of Trans Fatty Acids in Foods and the Effect on Human Health of the Consumption of Trans Fatty Acids," *EFSA Journal*, 81:1–49, 2004.
 64. Dietary Guidelines Advisory Committee, *Report of the Dietary Guidelines Advisory Committee on Dietary Guidelines for Americans, 2005*, Washington, DC: HHS, 2005; <http://www.health.gov/dietaryguidelines/dga2005/report/default.htm>.
 65. Dietary Guidelines Advisory Committee, *Report of the Dietary Guidelines Advisory Committee on Dietary Guidelines for Americans, 2010*, Washington, DC: USDA, Agricultural Research Service, 2010; <http://origin.www.cnpp.usda.gov/DGAs2010-DGACReport.htm>.
 66. Memorandum from M. Pfeil to M. Honigfort, June 11, 2015.
- Dated: June 12, 2015.
- Leslie Kux,**
Associate Commissioner for Policy.
[FR Doc. 2015–14883 Filed 6–16–15; 8:45 am]
BILLING CODE 4164–01–P
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- DEPARTMENT OF HEALTH AND HUMAN SERVICES**
- Food and Drug Administration**
- [Docket No. FDA–2012–N–0369]
- Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Under the Federal Import Milk Act**
- AGENCY:** Food and Drug Administration, HHS.
- ACTION:** Notice.
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- 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 July 17, 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 0910-0212. 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.

Under Federal Import Milk Act (FIMA) (21 U.S.C. 141-149), milk or cream may be imported into the United States only by the holder of a valid import milk permit (21 U.S.C. 141). Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F (21 U.S.C. 142).

Our regulations in part 1210 (21 CFR part 1210) implement the provisions of FIMA. Sections 1210.11 and 1210.14 require reports on the sanitary conditions of, respectively, dairy farms

and plants producing milk and/or cream to be shipped to the United States.

Section 1210.12 requires reports on the physical examination of herds, while § 1210.13 requires the reporting of tuberculin testing of the herds. In addition, the regulations in part 1210 require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22). Section 1210.20 requires that an application for a permit to ship or transport milk or cream into the United States be made by the actual shipper. Section 1210.23 allows permits to be granted based on certificates from accredited officials.

In the **Federal Register** of March 25, 2015 (80 FR 15794), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Section	Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.11	FDA 1996; Sanitary Inspection of Dairy Farms.	2	200	400	1.5	600
1210.12	FDA 1995; Physical Examination of Cows.	1	1	1	0.5 (30 minutes)	0.5
1210.13	FDA 1994; Tuberculin Test	1	1	1	0.5 (30 minutes)	0.5
1210.14	FDA 1997; Sanitary Inspections of Plants.	2	1	2	2	4
1210.20	FDA 1993; Application for Permit.	2	1	2	0.5 (30 minutes)	1
1210.23	FDA 1815; Permits Granted on Certificates.	2	1	2	0.5 (30 minutes)	1
Total	607

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1210.15	2	1	2	0.05	0.1

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

The estimated number of respondents and hours per response are based on our experience with the import milk permit program and the average number of import milk permit holders over the past three years. We estimate that two respondents will submit approximately 200 Form FDA 1996 reports annually, for a total of 600 responses. We estimate the reporting burden to be 1.5 hours per

response, for a total burden of 607 hours.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Because we have not received any Forms FDA 1994 and 1995 in the last 3 years, the Agency estimates no more than one will be submitted annually. We estimate the reporting burden for each to be 0.5 hours per response for a total burden reporting burden of 0.5 hours each.

We estimate that two respondents will submit one Form FDA 1997 report

annually, for a total of two responses. We estimate the reporting burden to be 2 hours per response, for a total burden of 4 hours. We estimate that two respondents will submit one Form FDA 1993 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hours per response, for a total burden of 1 hour. We estimate that two respondents will submit one Form FDA 1815 report annually, for a total of two responses. We estimate the reporting burden to be 0.5 hours per response, for a total burden of 1 hour.

With regard to records maintenance, we estimate that approximately two recordkeepers will spend 0.05 hours annually maintaining the additional pasteurization records required by § 1210.15, for a total of 0.10 hours annually.

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by us (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of business activities.

Dated: June 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-2347]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Food and Cosmetic Export Certificate Applications Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, "Food and Cosmetic Export Certificate Applications Process" 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On April 23, 2015, the Agency submitted a proposed collection of information entitled, "Food and Cosmetic Export Certificate Applications Process" 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 0910-0793. The approval expires on May 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: June 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-14879 Filed 6-16-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1794]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Ads

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 July 17, 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-New and title "Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-To-Consumer Prescription Drug Ads." 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, PRASStaff@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.

Impact of Ad Exposure Frequency on Perception and Mental Processing of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Ads; OMB Control Number 0910-NEW

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

In a typical promotional campaign, consumers may be exposed to a direct-to-consumer (DTC) prescription drug ad any number of times. Perceptual and cognitive effects of increased ad exposure frequency have been studied extensively using non-drug ads. For instance, one study demonstrated that a commercial message repeated twice generates better recall than a message broadcast only once (Ref. 1). Another study demonstrated that increased ad exposures improve product attitudes and recall for product attributes, particularly when the substance of the repeat messages is varied (Ref. 2). Generally, it has been argued that first exposure to an ad results in attention, second exposure affects learning of the advertised message, and third and