67. Leslie Kux, Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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
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.
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annualy, 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 193 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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 proposed collection of information, “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, PRAssist@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.

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; 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...