further assume that the 1,518 cosmetic product establishments may not maintain all of the records recommended by the draft guidance. Thus, for purposes of this analysis, we assume that 1,518 establishments will keep the records recommended by the draft guidance, when it is finalized, as reported in table 2, column 2. We further assume that if multiple products are produced in the same facility, the written procedures and recordkeeping will be shared among the multiple products.

We base our estimates of the number of records per recordkeeper and the average burden per recordkeeping reported in columns 3 and 5 of tables 1 and 2 on our experience with good manufacturing practices used to control the identity and composition of food and dietary supplements and to limit contaminants and prevent adulteration, as well as our estimate of the burden of similar recordkeeping activities described in the dietary supplement final rule published in the **Federal Register** of June 25, 2007 (72 FR 34752 at 34916) (the June 25, 2007, final rule), that established, in part 111 (21 CFR part 111), the minimum good manufacturing practices necessary for dietary supplements. For the recordkeeping recommendations listed in table 2, the recordkeeping occasions consist of frequent brief entries of dates, temperatures, monitoring results, or documentation that specific actions were taken. Information might be recorded a few times a day, week, or month. Because the records burden involves frequent brief entries, we did not attempt to estimate the actual number of recordkeeping occasions for these activities. We entered one as the default for the number of records per recordkeeper and we calculated the average burden per recordkeeping in column 5 based on the reported burden of similar provisions estimated in the June 25, 2007, final rule, averaged across the 1,460 firms covered by that final rule.

The estimates for the recordkeeping burdens presented here are averages. We anticipate that the time spent to develop written procedures and recordkeeping would vary based on the type of cosmetic product manufactured. The estimated burdens for developing recordkeeping includes record maintenance, periodically reviewing records to determine if they may be discarded, and any associated documentation for that activity.

This draft guidance also refers to previously approved collections of information found in our regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information in our recall regulations in 21 CFR part 7 have been approved under OMB control number 0910–0249. The collection of information in 21 CFR 70.25, which requires that color additives subject to certification be labeled with the lot number assigned by the Color Certification Branch, has been approved under OMB control number 0910–0016.

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–25957 Filed 10–9–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3543]

Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on research entitled ''Quantitative Information in Direct-to-Consumer Television Advertisements.'' The objective of this research is to test consumers' understanding of quantitative information about prescription drugs in DTC television advertisements (ads).

DATES: Submit either electronic or written comments on the collection of information by December 14, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3543 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Quantitative Information in Direct-to-Consumer Television Advertisements.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including

the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Quantitative Information in Direct-to-Consumer Television Advertisements 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.

A previous FDA study found that simple quantitative information could be conveyed in direct-to-consumer (DTC) television ads in ways that increased consumer's knowledge about the drug (OMB control number 0910–0663, ''Experimental Study: Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs'').[1] However, this research only tested simple information (*e.g.,* one clinical trial, comparison to placebo). Drug information can be much more complicated (*e.g.,* complicated endpoints, multiple study arms). The following studies are designed to address the question of whether consumers can use more complicated information when assessing prescription drug information in television DTC ads. These studies will build on previous research by: (1) Examining more complicated quantitative information, (2) examining quantitative information for both benefits and risks, and (3) examining how visuals designed to represent efficacy interact with quantitative information.

The objective of this project is to test consumers' understanding of quantitative information about prescription drugs in DTC television ads. In study 1, we plan to examine experimentally the presence and complexity of quantitative benefit and risk information in DTC television ads (table 1). We hypothesize that, replicating past studies, adding simple quantitative information about benefits and risks will lead to increased understanding among consumers. We will test whether adding complex quantitative information results in the same outcomes as simple quantitative information or whether it is too much quantitative information for consumers to process. In study 2, we plan to examine experimentally the presence of quantitative benefit information and how the ad visually represents efficacy (by having no images, images that accurately reflect the improvement in health that could be expected with treatment, or images that overstate the improvement in health that could be expected with treatment (table 2). We hypothesize that overstated images of improvement will lead consumers to overestimate the drug's efficacy; however, adding a quantitative claim may moderate this effect. To test these hypotheses, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample sizes described below, we will have sufficient power to detect small- to medium-sized effects in each study.

All participants will be 60 years of age or older. We will exclude individuals who work in healthcare or marketing. We selected a sample of participants 60 years and older to increase the likelihood that participants will be interested in the fictitious study drug and therefore motivated to pay attention to the ad during the study. The studies will be conducted with an Internet panel.

In both studies, participants will be randomly assigned to one experimental condition and view the corresponding television ad. The ad will be for a fictitious drug to treat cataracts. The ads will be created and pretested to ensure that consumers perceive different levels of complexity across the ads in study 1, and different levels of image accuracy in study 2. ''Pretests for a Study on Quantitative Information in Direct-to-Consumer Television Advertisements'' will be submitted under OMB control number 0910–0695. After viewing the ad twice, participants will complete a questionnaire that assesses consumers' understanding of the drug information, their retention of the information, and their perceptions of the drug. We will also measure covariates such as demographics and numeracy. The

[1] O'Donoghue, A.C., H.W. Sullivan, K.J. Aikin, *et al.* ''Presenting efficacy information in direct-to-consumer prescription drug advertisements.'' *Patient Education and Counseling,* vol. 95(2), pp. 271–280, 2014.

questionnaires are available upon request.

TABLE 1—STUDY 1 DESIGN

		Quantitative risk claim		
Quantitative Efficacy Claim	No. Yes: simple (*e.g.*, reduced pain in 83% of patients). Yes: complex (*e.g.*, reduced pain by 30% in 83% of patients).	No ...	Yes: General Statement (*e.g.*, seen in less than 1% of patients).	Yes: Frequencies for Each Risk

TABLE 2—STUDY 2 DESIGN

			Images of improvement	
Quantitative Benefit Claim	No. Yes.	None	Accurate improvement in health conveyed in images.	Overstated improvement in health conveyed in images.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]—STUDY 1

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	.05 (3 min.)	76
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	.33 (20 min.)	297
Total			2,413		373

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]—STUDY 2

Activity	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Sample outgo	15,130				
Number to complete the screener (10%)	1,513	1	1,513	.05 (3 min.)	76
Number eligible for survey (70%)	1,059				
Number to complete the survey (85%)	900	1	900	.33 (20 min.)	297
Total			2,413		373

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

Dated: October 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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