TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Information collected	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					123
2. Testing of HPHC Quantities in Products:					
Cigarette Filler	78	0.79	62	9.42	584
Roll-Your-Own	39	0.21	8	9.42	75
Smokeless	52	0.21	11	12.06	133
Total					792
3. Testing of HPHC Quantities in Mainstream Smoke:					
Cigarette: International Oraganization for Standardization (ISO) Regimen.	78	0.79	62	23.64	1,466
Cigarette: Health Canada Regimen	78	0.79	62	23.64	1,466
Total					2,932
4. Additional HPHC reports: [2]					
Cigarette Filler	78	2.56	200	1	200
Roll-Your-Own	39	5.12	200	1	200
Smokeless	52	3.84	200	1	200
Total					600
Total Section 904(c)(1) Reporting Burden Hours					4,447

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] HPHC reports for identical products (*e.g.,* under different brand or sub-brand names) in which the HPHC measures will be the same as the original report.

Table 1 contains estimates for new product information received annually under section 904(c)(1) of the FD&C Act. Manufacturers must report HPHC information under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce. The total annual burden for this collection of information is estimated to be 4,447 hours. The burden estimate for this collection of information includes the time it will take to test the products and prepare the HPHC report. Table 1 indicates that 169 respondents will submit HPHC reports when new products enter the market.

Section 1 of the table addresses the time required for manufacturers to report their company information. We estimate that the time to report HPHC information is no more than 1.82 hours for cigarettes, 0.42 hours for roll-your-own, and 0.63 hours for smokeless tobacco products for each response regardless of whether the paper or electronic form (Form FDA 3787) is used. (The estimated times to report smokeless tobacco products (0.63 hour) and roll-your-own tobacco products (0.43 hour) are lower than the estimated reporting time for cigarette products because fewer HPHCs are normally reported for these two types of products. The total annual burden for reporting company and product information is 123 hours.

Section 2 of the table addresses the time required for manufacturers to test quantities of HPHCs in their products. The burden hour estimates include the time needed to test the tobacco products, draft testing reports, and draft the report for FDA. For cigarette filler, smokeless, and roll-your-own products, we estimate the burden to be 792 annual burden hours. The burden for each product type reflects our estimate of the time to test the tobacco products (*i.e.,* carry out laboratory work).

In addition to addressing the time required to report information and test quantities of HPHCs in tobacco products, section 3 of table 1 addresses the time required for manufacturers to test quantities of HPHCs in cigarette smoke. The burden estimates include testing the tobacco products, drafting testing reports, and drafting the report for FDA. We estimate the annualized burden for this section to be 2,932 hours. The annual burden reflects our estimate to test the tobacco products (*i.e.,* carry out laboratory work). The burden estimate assumes that manufacturers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens described in the table.

As stated previously, FDA expects to receive 600 additional HPHC reports at 1 hour per response for a total of 600 hours. The estimated total annual burden for the reporting of HPHC under section 904(c)(1) of the FD&C Act is 4,447 hours.

Dated: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0735]

Agency Information Collection Activities; Proposed Collection; Comment Request; Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs

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 ''Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs.'' This study will examine how the size and presentation of superimposed text (supers) influences the comprehension of direct-to-consumer (DTC) television advertisements for prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by May 9, 2016.

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–2016–N–0735 for ''Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs.'' 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.

Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs—OMB Control Number 0910—NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes 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(d)(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.

The proposed study seeks to extend previous research on the effects of supers in general print and television advertising to today's modern DTC pharmaceutical promotion. Although earlier research on the effects of supers in other consumer settings suggests that altering text size can influence consumer comprehension of information, it is unclear if these findings extend to DTC promotion of prescription drugs and are applicable over 20 years later when viewing promotional materials using today's modern technologies (*e.g.,* tablets). Moreover, other factors such as text/background contrast may also influence both the understanding of the superimposed information (Ref. 1) and the effects of text size. The proposed research seeks to update these earlier findings and also to answer new questions concerning presentation of supers.

Part of FDA's public health mission is to ensure the safe use of prescription drugs; therefore, it is important that the information provided in DTC promotion is clear and understandable for consumer audiences, avoids use of deceptive or misleading claims, and

achieves ''fair balance'' in presentation of benefits and risks. For example, varying presentation formats including type size, bulleting, amount of white space, and use of ''chunking'' or headlines can all influence consumer perceptions of information (Ref. 2). A systematic review of presentation formats in prescription drug labeling found that these ''clear communication'' characteristics positively influenced consumer's comprehension of information and prescription drug behaviors (*i.e.,* adherence) (Ref. 3). In one randomized controlled study, young and older adults were presented with 12 otherwise identical over-the-counter drugs bottled with varied container labels along various dimensions, one of which was text size (7 vs. 10 point). While younger participants performed equally well with both font sizes, elderly populations had significantly reduced recall and comprehension when exposed to the smaller text size (Ref. 4). Another study found that both young and older populations preferred the larger text size and that patients read labels with larger font more rapidly and accurately than labels with smaller font (Ref. 5). Although these studies were specific to prescription drug container labels, it is plausible that the effects of font sizes would be applicable to drug promotion.

Some early research in the late 1980s and 1990s examined the size of supers in print and television advertising topics outside of prescription drugs (Refs. 6, 7, and 8). These studies all generally found that the text size of the super was associated with comprehension, such that the larger text sizes increased understanding of the material (and, conversely, smaller text sizes interfered with comprehension). For example, Foxman and colleagues (Ref. 6) found that whereas ''small'' text size (> ½ inch size) was associated with accurate comprehension for 59 percent of respondents, ''large'' text size (> ½ inch size) was associated with comprehension for 79 percent of respondents. Studies by other researchers (Refs. 7 and 8) found similar patterns such that increasing the text size of supers generally corresponded with increased comprehension.

We know of no studies that have examined other commonly variable factors, such as text/background contrast, that may interact with text size to influence comprehension. Early research on text readability determined that the contrast between text and background has a consistent but small effect. Specifically, while the contrast of color has a small effect (Ref. 9), the contrast in brightness, or luminance, makes the largest difference (Ref. 10). These studies showed that black text on a white background results in the highest readability (Ref. 11), but that other effects of color contrasts are unclear (Ref .1). Some studies have demonstrated that contrast interacts with text size, such that contrast becomes a more important discriminator as the text size decreases (Ref. 12).

The earlier research on supers is limited in their applicability to today's DTC promotion in several ways. None of these studies specifically focused on prescription drug promotion, but rather explored the effects of superimposed text in a variety of social and consumer advertising contexts. Another limitation is that these earlier studies were conducted with populations (*i.e.,* undergraduate students) that are not representative of today's prescription drug users. It is not clear if the effects of supers would translate to older adult populations, who represent the greatest proportion of prescription drug users (Ref. 13). Perhaps most importantly, it is unknown if the effects of supers would be found today, considering the prevalent use of modern technologies, including large (40+ inches) TV screens and personal tablets for online viewing. Our proposed study seeks to address these unanswered questions regarding the use of supers in prescription drug promotion.

II. General Research Questions

1. Does the size of the superimposed text, the contrast behind the superimposed text, and/or the device type influence the noticeability, recall, and perceived importance of the super information?

2. Does the size of the superimposed text, the contrast behind the superimposed text, and/or the device type influence the recall of and attitudes toward the promoted drug?

3. Are there any interaction effects among any combination of independent variables?

III. Design

To test these research questions, we will conduct one randomized controlled study. We will examine reactions to supers in a fictitious DTC prescription drug promotional video on two types of viewing devices with a general population sample. The study design will be a $3 \times 2 \times 2$ factorial design, where participants are randomly assigned to 1 of 12 experimental study arms differentiated by:

- Super text size (small, medium, large);
- Device type (television, tablet);
- Super text contrast (high, low).

TABLE 1—DESIGN AND CELL SIZES FOR MAIN STUDY [1]

Device Type	TV			Tablet			Total
Super Size	Small	Medium	Large	Small	Medium	Large	
Contrast:							
High	106	106	106	106	106	106	636
Low	106	106	106	106	106	106	636
Total	212	212	212	212	212	212	1,272

[1] The sample will be split evenly across 3 cities (Los Angeles, CA; Cincinnati, OH; and Tampa, FL), with 424 participants per city.

For both the pretest and main study, we will work with two market research firms to recruit adult participants and conduct in-person data collection in three U.S. cities: Los Angeles, CA; Cincinnati, OH; and Tampa, FL. In addition to our aim for regional variation, we selected these three cities with the aim of recruiting a sample that is diverse on gender, race/ethnicity, education, and age characteristics.

Participants from the general population will be invited to a market research facility to watch one video for a fictional prescription drug that treats asthma. In-person administration of study procedures will enable us to control the television and tablet watching experience in terms of size, distance, and other variables. Participants will watch the video twice and then answer questions addressing recall of risks and benefits, perceptions of risks and benefits, and questions

regarding the salience of information in text. The questionnaire is available upon request. Participation is estimated to take approximately 20 minutes.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance.

Pretesting will take place before the main study to select super sizes for the main study and to evaluate the procedures and measures that will be used. We will exclude individuals who work in health care or marketing settings because their knowledge and experiences may not reflect those of the average consumer. We conducted a priori power analyses to determine sample sizes for the pretest and the main study.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretesting					
No. to complete the screener (assumes 50% eligible).	338	1	338	0.08 (5 minutes)	27
No. of completes	240	1	240	0.33 (20 minutes)	79
Main Study					
No. to complete the screener (assumes 50% eligible).	1,785	1	1,785	0.08 (5 minutes)	143
No. of completes	1,272	1	1,272	0.33 (20 minutes)	420
Total					669

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

IV. References

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Dated: March 2, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0712]

Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease, a Patient-Reported Outcome, for the Measurement of Severity of Respiratory Symptoms in Stable Chronic Obstructive Pulmonary Disease: Qualification for Exploratory Use; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Evaluating Respiratory Symptoms in Chronic Obstructive Pulmonary Disease, a Patient-Reported Outcome, for the Measurement of Severity of Respiratory Symptoms in Stable Chronic Obstructive Pulmonary Disease: Qualification for Exploratory Use.'' This draft guidance provides a statement of qualification for exploratory use for the evaluating respiratory symptoms in chronic obstructive pulmonary disease (E–RS: COPD), a patient-reported outcome instrument, and summarizes the concept of interest and context of use (COU) for which the tool is qualified through the Center for Drug Evaluation