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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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes” to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Shanil Haugen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G104, Silver Spring, MD 20993–0002, 301–796–0301.

SUPPLEMENTARY INFORMATION:

I. Background

Flexible gastrointestinal endoscopes and accessories (including valves and other devices used for irrigation) are class II devices regulated under 21 CFR 876.1500, *Endoscope and accessories*. During a colonoscopy or esophagogastroduodenoscopy (EGD), clinicians often use an irrigation system comprised of a water bottle, tubing, valves, etc., to supply irrigation for the procedure. Clinicians typically do not clean and sterilize all components of the irrigation system after each procedure;

e.g., they may use a single water bottle for an entire day of procedures without reprocessing the water bottle between patients. This practice raises the risk of cross-contamination between patients, because the water bottle and associated tubing and connectors can become contaminated with the fluids and materials (e.g., blood, stool) of patients that travel back through the irrigation system channels and tubing during the procedure.

FDA is providing this guidance to highlight the cross-contamination risk posed by specific practices and types of irrigation valves and accessories; clarify terminology used to describe irrigation system components; and outline recommended mitigation strategies (e.g., device design, labeling) meant to reduce the risk of cross-contamination between patients from the day-use of irrigation system tubing, valves, and accessories. FDA announced the availability of the draft guidance in the **Federal Register** of January 20, 2015 (80 FR 2711). Interested persons were invited to comment by April 20, 2015, and the final guidance includes revisions intended to address the comments received.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Mitigating the Risk of Cross-Contamination From Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. Persons unable to download an electronic copy of “Mitigating the Risk of Cross-Contamination from Valves and Accessories Used for Irrigation Through Flexible Gastrointestinal Endoscopes” may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1400054 to

identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: November 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–28604 Filed 11–28–16; 8:45 am]

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; Submission for Office of Management and Budget Review; 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 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 December 29, 2016.

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 oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–NEW nd title Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs. 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, *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.

Superimposed Text in Direct-to-Consumer Promotion of Prescription Drugs—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(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 superimposed text (supers) in advertising to today's modern direct-to-consumer (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 text information in advertising topics outside of prescription drugs (Refs. 6, 7, and 8). These studies all generally found that text size was associated with comprehension, such that 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 (<1/2 inch size) was associated with accurate comprehension for 59% of respondents, "large" text size (>1/2 inch size) was associated with comprehension for 79% 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. Our proposed study seeks to address these unanswered questions regarding the use of supers in prescription drug promotion.

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?

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 x 2 x 2 factorial design, where participants are randomly assigned to one 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

Device type	TV			Tablet			Total
	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

Note: The sample will be split evenly across three 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 (ANOVA).

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 healthcare 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.

In the **Federal Register** of March 9, 2016 (81 FR 12503), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received 10 comments total. Six comments were outside the scope of the proposed research (“Ban DTC”), leaving four substantive comments.

1. Abbvie

a. *Comment:* Mobile users can change font size and viewing size—we should incorporate this into our study.

Response: Although the font size for certain text (such as newspaper articles) or closed captioning text size can be changed on a tablet, supers within a developed video cannot be manipulated. Participants will be allowed to hold the tablet as they normally would, but it is important to establish experimental control over many user settings to avoid threats to internal validity. Thus, font and viewing size will be standardized for this study.

b. *Comment:* Recommend looking at use of TV and mobile devices concurrently, as some people use them this way.

Response: This is a good suggestion for future research, but is out of scope for the current study.

2. Lilly

a. *Comment:* Generally supportive; research objectives and study approach are reasonable.

Response: Thank you.

b. *Comment:* Recommend showing supers in black box at bottom of the screen and not superimposing them over moving, contrasting color field to mimic common practices in television commercial advertising.

Response: Our high contrast condition indeed presents the supers in white font on a black background at the bottom of the screen. Our low contrast condition shows lettering over the moving scenes because not all advertisements show their supers in a black banner.

c. *Comment:* Lilly requests clarity about how the size of text and level of contrast were developed when the agency reports the results of the study.

Response: We used cognitive interviews and will use the pretest to make these determinations. We will be sure to include this information when we report the results of the study.

d. *Comment:* Recommend qualitative pre-test instead of quantitative pretest.

Response: We fulfilled this suggested purpose with a set of nine cognitive

interviews that were conducted in April.

e. *Comment:* Request clarity about quota sampling and other techniques we may plan to use to ensure a diverse sample. Also suggest groups of at least 50 in each cell for analysis purposes.

Response: As this study is not intended to be nationally representative, we will not employ strict quota sampling procedures. However, we will work closely with our recruitment firms to monitor recruitment and ensure that our sample is diverse with regard to factors including race, education, age and gender. Further, selection of our three U.S. cities for data collection (Los Angeles, Cincinnati and Tampa) was purposive to help achieve diversity on these factors.

To answer the second part of the comment, we are aware of no statistical or research standard that specifies that groups must contain 50 individuals. However, we conducted power analyses and determined that in order to have enough power for the proposed statistical tests, we will exceed this number per experimental cell.

f. *Comment:* Recommends replacing the pre-test question about the importance of the text information (Question 5) with a question such as “how noticeable or legible was the text information?”

Response: We agree that the noticeability and legibility of the text information is important, and we have other questions that address this. We are specifically interested in the perceived importance of the text information as a moderator variable.

g. *Comment:* Recommends removing semantic differential questions (Question 9) and essentially any questions that ask about perceptions because it is a pretest.

Response: Our pretest study is not designed to test the main study questionnaire. Rather, the main purposes of the pretest are to (1) test consumer perceptions of superimposed-text size with the aim of choosing perceptibly different levels of size (small, medium, large) for use in the main study; and (2) test our planned

procedures for implementation of the intervention (TV and tablet) and in-person data collection. However, to make the most use of our resources, we also plan to test the properties of certain main study survey items (e.g., means, ranges, etc.) to ensure the utility of the items for use in the main study.

h. *Comment:* Calls out an inconsistency in terms of how many times participants will view the ad.

Response: Thank you for noting that discrepancy. Participants will view the ad once. We have corrected all materials to reflect this change. Lilly recommends showing it twice. We agree that if the goal is to learn about user experience (preferences and such, or trying to improve the presentation) then two or more viewings makes sense. However, our goal is to test differences in cognitive processing based on the varied size/contrast presentations of the supers. Thus, we do not want to artificially enhance the scrutiny participants pay to the ad above and beyond the experimental situation. For example, small supers may interfere with cognitive processing as hypothesized, but this interference may be overcome upon a second viewing. In a real world viewing situation, consumers rarely see an ad two times in a row.

i. *Comment:* Question 12: Attributes are very similar and will be duplicative.

Response: The three survey items for question 12 (attitudes towards the ad) are conceptually similar and will be used as a multi-item scale. Conventionally, three items is the minimum recommended to assess inter-item reliability.

j. *Comment:* Question 12 and 14: Suggest bolding or underlining “drug” or “ad” in these questions to differentiate them for participants.

Response: We agree and have added language to the survey items to better make this distinction. For items specific to attitudes towards the drug we now begin the item with “Overall, DRUG X is . . .” whereas items about the ad begin with “Overall, the ad was . . .”

k. *Comment:* Would be interesting to include an open-ended question about whether any additional information could have or should have been

provided in the ad, such as accessibility to the drug, information about the disease, etc.

Response: These are great ideas and would provide additional information about various communication issues relevant to DTC television promotion. However, we regret that we must make difficult choices about what to include and not include in this study and these issues fall outside the scope of the current research questions.

3. Merck

a. *Comment:* FDA’s execution may not yield useful data. For example, we are examining TV and tablet use, but people may be viewing promotion on mobile devices.

Response: We agree that the ways in which people view their media are multiplying and that we have not captured all of them. However, rather than simply study superimposed text on a television screen, we opted to add an examination of viewing on a tablet, which is an increasingly popular option for viewing shows. We regret that we do not have the opportunity to explore viewing on all possible new technologies, but we believe that the current study will offer insights above and beyond the television screen.

b. *Comment:* Prior to the implementation of results from individual studies on the content, format, and presentation of information in DTC advertisements on television, FDA should conduct research on the combination of all of the individual factors.

Response: This comment is outside the scope of the present project. It is not directed at the improvement of the study and does not appear to require the abandonment of the current study.

4. GlaxoSmithKline (GSK)

a. *Comment:* Allowing participants to view the TV at the distance they usually view it and to interact with the tablet the way they ordinarily do would better reflect a real-world experience.

Response: We agree that these details are important to consider when conducting valid research. We must make a decision between the trade-off of experimental control and real-world

generalizability. We have attempted to do this by setting up the television and chair in the room at the average distance that people tend to sit from their televisions in their living room and instructing participants to wear glasses or contact lenses if needed. Television viewing is a more fixed experience than more modern technologies. We also agree that allowing individuals to hold the tablet or place it on a table as they normally would is appropriate for both experimental control and ecological generalizability.

b. *Comment:* Including a medium contrast instead of just a high and low contrast may be informative.

Response: We appreciate this comment because we considered it when designing the study. We decided to use only high and low contrast in the study because our main variable of interest in this particular study is the size of the text. Thus, we are expending resources to attempt to determine multiple sizes of text to test in order to get a fuller appreciation of the role of text size in DTC promotion. We have found in past studies that identifying a medium level is difficult (e.g., OMB Control No. 0910–0695) and chose in this study to focus on size rather than contrast. That said, we do feel that contrast is valuable enough to add as a variable of interest, so we are planning to devote two conditions to it.

c. *Comment:* It would be useful if the questionnaire is posted along with the notice on regulations.gov.

Response: We are happy to provide the questionnaire to anyone who requests it.

d. *Comment:* Suggests an FDA-Industry working group might be helpful in the furtherance of this research.

Response: This is an intriguing idea and may have merit after we obtain empirical data that is specifically applicable to DTC promotion. Without this data, it is unclear what this working group would contribute. We will consider this idea in further detail upon interpretation of results.

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 (in hours)	Total hours
Pretesting					
Number to complete the screener (assumes 50% eligible).	338	1	338	0.08 (5 minutes)	27

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
Number of completes	240	1	240	0.42 (25 minutes)	101
Main Study					
Number to complete the screener (assumes 50% eligibility).	1,785	1	1,785	0.08 (5 minutes)	143
Number of completes	1,272	1	1,272	0.42 (25 minutes)	534
Total hours					805

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

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.

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Dated: November 22, 2016.

Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016–28733 Filed 11–28–16; 8:45 am]
BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–F–3880]

Novus International, Inc.; Filing of Food Additive Petition (Animal Use); Correction

AGENCY: Food and Drug Administration, HHS

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice entitled “Novus International, Inc.; Filing of Food Additive Petition (Animal Use)” that appeared in the **Federal Register** of November 8, 2016 (81 FR 78528). The document announced that Novus International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food. The document was published with the incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115, lisa.granger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, November 8, 2016, in FR Doc. 2016–26922, on page 78528, the following correction is made: On page 78528, in the first column, “Docket No. FDA–2014–F–0452” is corrected to read “Docket No. FDA–2016–F–3880”.

Dated: November 22, 2016.

Leslie Kux,
Associate Commissioner for Policy.
 [FR Doc. 2016–28656 Filed 11–28–16; 8:45 am]
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