DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Hearing, Aging, and Direct-to-Consumer Television Advertisements

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: Submit either electronic or written comments on the collection of information by January 22, 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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Hearing, Aging, and Direct-to-Consumer Television Advertisements.'' 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:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Hearing, Aging, and 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.

Older adults use a disproportionate number of prescription drugs (Ref. 1) and watch more television than other age groups (Ref. 2). Age-related changes in hearing are common (Refs. 3–5) and, depending on their severity, influence the understanding of speech. Direct-To-Consumer (DTC) television advertisements (ads) contain large amounts of complex information about prescription drug treatments that may be particularly relevant to a population that is experiencing some level of hearing loss. Moreover, much of the information in these ads is conveyed by voiceover, meaning that the audio channel is the only way to receive the information. Although people with serious hearing loss may compensate by using closed captioning (which may or may not be available for ads) or hearing aids, some individuals experience the effects of hearing loss without realizing that it is the cause and others choose not to use external compensatory aids (Ref. 6). For these reasons, FDA is proposing research to investigate how people at various ages and levels of hearing ability comprehend DTC ads.

Sponsors of DTC ads cannot control the hearing abilities of their audiences. Nonetheless, researchers have identified several aspects of DTC ads within their control that influence the understanding of speech in individuals who experience aging-related hearing loss. First, frequency thresholds differ as people age—that is, older adults are not able to hear higher frequencies as well (Refs. 7, 8). Second, DTC television ads contain a risk statement of the most serious and most common side effects, called ''the major statement.'' FDA regulations require that the major statement must be included in at least the audio portion of the ad (Ref. 9). The risks of a medical product often include highly technical medical terms that should be transformed into consumer-friendly language to convey the risks appropriately. This is easier in some cases than in others. In addition, there are techniques to help reduce the complexity of the major statement, such as maintaining active voice, reducing instances where words need clarification from other later words in the broadcast, and using shorter sentences. Third, television ad spots are typically bought in increments of 15 seconds, leading to a preponderance of 30- and 60-second ads, and some 75-second ads when risk information is especially dense. In order to fit the required information into this time frame, the audio presentation speed may be adjusted to be faster or slower. Research has shown that fast speech is more difficult to understand than slower speech, even for healthy young adults (Ref. 10).

Thus, we propose to examine the effects of three aspects of DTC ads (voice frequency, complexity of major statement, and speed of major statement) on the comprehension of the ads among four different age groups of individuals. Because hearing losses begin to occur as people age, we will examine a group of middle-aged adults (40–50 years), young-old adults (60–74 years), and old-old adults (75+ years), and a group of young adults (18–25 years) as a control. The use of young adults as a control group is common in studies of age changes in memory, cognition, and hearing (Refs. 11–14). We expect a progression of hearing loss across the lifespan, but that is not the focus of this study. Our primary outcomes will be verbatim and gist memory, and confidence in memory judgments, but we will also seek to apply findings from previous studies showing age changes in hearing ability (Refs. 15, 16) to the particular situation of DTC ad viewing.

It is important to note that despite hearing and cognitive losses, older adults generally use linguistic context well. That is, they are as good as or even better than younger adults at using context to determine what they are hearing. They are also skilled at using the intonation of words, which words are stressed, where pauses occur, and how words are lengthened before pauses, all components of something called the prosody of language (Ref. 17). Thus, even though older adults generally perform worse than younger adults with rapid speech, older adult recall of sentences is still relatively high, at 80 percent, presumably because older adults use linguistic context. Moreover, to approximate real DTC ads, participants will view an ad that has a typical amount of superimposed text, some of which may repeat the information in the audio. Our task thus involves viewing realistic DTC ads, which provide more context than lists of unrelated words or sentences, as often found in laboratory experiments. Thus, it is an open question whether hearing loss will impede the comprehension of DTC ads or whether the ability to make use of context will counteract these decrements across the lifespan.

II. General Research Questions

1. How do hearing and cognitive declines in older adults affect comprehension of DTC television ads, and the major statement in particular?

2. How do the frequency, speed, and complexity of the major statement influence the comprehension of the major statement and DTC ads as a whole?

3. How do hearing and cognitive declines interact with the frequency, speed, and complexity of the major statement to affect the comprehension of DTC ads?

III. Design

To test these research questions, we will examine four groups of adults and manipulate three variables as shown in table 1.

TABLE 1

Age	Speed	Voiceover frequency				Total
		Male (low frequency)		Female (high frequency)		
		Organization of major statement		Organization of major statement		
		Simple	Complex	Simple	Complex	
Young Adults (18–25)	Low Speed	33	33	33	33	132
	High Speed	33	33	33	33	132
Middle-Aged (40–50)	Low Speed	33	33	33	33	132
	High Speed	33	33	33	33	132
Young-Older (60–75)	Low Speed	33	33	33	33	132
	High Speed	33	33	33	33	132
Old-Older (OO; 75+)	Low Speed	33	33	33	33	132
	High Speed	33	33	33	33	132
Total		264	264	264	264	1,056

Pretesting will take place before the main study to evaluate the hearing assessment procedures and questionnaire measures used in the main study. We will recruit adults who fall into one of four age brackets shown in table 1. We will exclude individuals who work in healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. A priori power analyses revealed that we need 640 participants for the pretest to obtain 80 percent power to detect a small effect size, and 1,056 participants for the main study to obtain 90 percent power to detect a small effect size. Data collection will take place in person.

For the pretest and main study, within each age group, participants will be randomly assigned to one of eight experimental conditions in a 2 (speed) $\times$ 2 (frequency) $\times$ 2 (complexity) design, as depicted in table 1. The study will include audiometric measurement of individual hearing ability to help determine if hearing declines account for any age group differences in reported comprehension or retention of ad information. During the scheduled appointment time, participants will receive a complete audiometric test performed by audiologists from the University of North Carolina Hearing and Communication Center, watch a fictitious DTC television ad twice, and answer questions in a survey. Participation is estimated to take approximately 45 minutes.

Questionnaire measures are designed to assess, for both risk and benefit information, verbatim memory, comprehension, gist memory, and confidence in memory and comprehension judgments. The draft questionnaire is available upon request.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the **Federal Register** of June 25, 2015 (80 FR 36545). Two comments were received. We will address the issues raised in each comment subsequently, beginning with those of AbbVie.

(Comment 1) The Agency should place research results in the context that older adults are diverse and increasingly involved in new technologies.

(Response 1) We agree that older adults are not homogenous. Regarding our focus on television ads, the fact that older people are increasingly able to look at advertisements online does not eliminate the fact that many continue to be exposed to television advertising and that advertising is not always presented with closed-captioning. We will ensure that we frame our research results in the proper context.

(Comment 2) A bias may exist in asking survey participants to self-declare ''a hearing loss'' as hearing loss can be viewed as a negative consequence/indicator of aging. Thus, those in older age groups may underestimate their true hearing loss as well as the need for some type of hearing aid or assistance.

(Response 2) We will not rely solely on self-reported hearing loss. We have arranged for trained audiologists to conduct in-person audiological assessments with validated approaches as well.

(Comment 3) As the Agency plans to test multiple variables and age groups, it is important to test these variables independently; testing only in combination with other variables or aggregating across age groups or variables may mask true drivers. Individual cells with a sample size of 33 are too small to compare to other individual cells. A minimum of 50 is necessary to understand individual variables within and across age groups.

(Response 3) We are aware of no statistical or research standard that specifies that groups must contain 50 individuals. We conducted power analyses to determine that 33 individuals per cell is adequate and statistically defensible for our study goals.

(Comment 4) The Introduction and Debriefing state that the study ''involves information about a drug that is not yet available for sale.'' However, survey questions 8, 10, 18, and 30 refer to respondents having access to the drug with verbiage such as ''even if you have never taken the drug,'' ''ask the doctor to prescribe Drug X,'' and ''have you seen any advertising for Drug X before today.'' Yet none of these could happen if Drug X is not yet available for sale.

(Response 4) We acknowledge that we are posing hypothetical possibilities in some questions that respondents should

not have previously experienced. We have changed the introduction to reference ''advertising for a new product'' rather than ''information about a drug that is not yet available for sale.'' However, using language such as ''even if you have never taken the drug'' will assure respondents that their answers are welcome even if they do not have direct experience with the drug. The question about asking the doctor to prescribe the drug measures behavioral intentions, not actual behavior related to the drug. The question asking whether they have seen an ad for the drug will allow us to capture false reporting tendencies.

(Comment 5) Question 13 refers to ''claims''. We suspect ''claim'' is not as readily understood by consumers as is the more general term ''information'' used in Question 17. Also, there are only minor differences in the wording of two recognition choices for Questions 13a vs. 13b; was this intended?

(Response 5) Thank you for your close review of the questionnaire. The two ad versions (simple and complex) are designed to include the same information but stated differently. Thus, these two questions (then 13a and 13b; now 14a and 14b) should be similar in nature and only two of the sub-items are stated differently (#2 and #4). Participants will see either question 14a or 14b depending on their experimental condition.

The next responses address issues raised by Eli Lilly and Company.

(Comment 6) What are the objectives of the pretest? The proposed sample size for the pretest (n = 640) appears excessive to test the procedural flow and survey procedures.

(Response 6) The pretest will be used to assess whether the instrument as a whole as well as individual sections work equally well across respondent groups (*e.g.,* age). In addition, the pretest will include manipulation checks as a main function of the task. The sample size for the pretest (640 participants equally split across the four age groups) was determined based on an assumption of a need for 80 percent power with an alpha of 0.10 to detect a small effect size. With eight experimental conditions across four age groups, the calculation resulted in a need for 20 individuals per cell, or 640 total participants.

(Comment 7) The age groups selected are logical, but why are people aged 51–59 excluded and why are 18–25 year olds selected as the control? ''Although 18–25 year olds as a control group might be common in studies of age changes in memory and hearing, this age group does not seem as relevant for pharmaceutical advertisements about cholesterol lowering drugs.'' Also, the age group of 60–75 should be capped at 74 to make sure the groups are mutually exclusive.

(Response 7) We agree that there is a likely slow progression of age-related hearing loss across the lifespan and if our focus was on this progression, we would want to include 50–59 year olds. The approach we are taking will ensure that we can see contrasts between younger and older people. We also have a middle-aged group to see whether any contrast between the youngest and oldest groups appears to be relatively linear or is curvilinear. Including the 50–59 year age group would not add substantial information to this design, although we do acknowledge that we will not be able to address when decline occurs if it appears to drop dramatically from our middle-aged group to our young-older age group.

We are including participants between 18–25 years as a baseline for our measurement of hearing ability, as that is an integral part of this research. The entire sample will be drawn from the general population, and although there may be distinct differences in potential interest in the advertised drug, we feel the addition of this younger group is worth measurement. We have included a question to assess whether participants have been diagnosed with high cholesterol and can use that as a proxy for interest, regardless of age. Thank you for pointing out the need to cap the young-old age group at 74 rather than 75 to ensure the groups are mutually exclusive.

(Comment 8) We advise caution in reporting results for individual cells (*e.g.,* 40–50 year old respondents who see an ad with a male voice, simple statement, low speed) due to the low sample size (n = 33). We recommend excluding results for a sample that has fewer than 50 respondents.

(Response 8) We are aware of no statistical or research standard that specifies that groups must contain 50 individuals. We conducted power analyses to determine that 33 individuals per cell is adequate and statistically defensible for our study goals.

(Comment 9) Because the Summary Brief of the project does not adequately provide details regarding the individual ads to be tested, we seek clarification on whether multiple ads will be tested and the variability of ad content. With greater variability of the ads tested, there is potential for a new source of bias to be introduced into the study.

(Response 9) We agree that extraneous variability should be kept to a minimum. For this study, the same base ad will be manipulated such that all else remains constant except for the gender of the voiceover announcer, the complexity of the risk information, and the speed at which it is stated. The visuals will be as similar as possible except for minimal differences in length of time on screen to account for the different lengths of the voiceover. The same male and female voice actors will record all variations of the ad.

IV. External Reviewers

In addition to public comment, Office of Prescription Drug Promotion solicited peer-review comments from academic researchers in fields relevant to the communication of DTC prescription drug information. We received responses and incorporated the thoughts of the following individuals:

Dr. Susan Blalock, University of North Carolina at Chapel Hill, School of Pharmacy

Dr. Robert McKeever, University of South Carolina, School of Journalism and Mass Communications

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample size described in table 2, we will have sufficient power to detect small-to-medium sized effects in 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
Cognitive Interview screener	96	1	96	0.08 (5 minutes)	8
Cognitive Interviews	9	1	9	1 (60 minutes)	9
Pretest screener	1,280	1	1,280	0.08 (5 minutes)	102

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretest	640	1	640	0.75 (45 minutes)	480
Main Study Screener	2,112	1	2,112	0.08 (5 minutes)	169
Main Study	1,056	1	1,056	0.75 (45 minutes)	792
Total	5,193	1	5,193		1,560

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

V. 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.

1. Zhong W., H. Maradit-Kremers, J.L. St. Sauver, et al., ''Age and Sex Patterns of Drug Prescribing in a Defined American Population.'' *Mayo Clinic Proceedings.* 88(7):697–707, 2013.
2. Depp C.A., D.A. Schkade, W.K. Thompson, D.V. Jeste. ''Age, Affective Experience, and Television Use.'' *American Journal of Preventative Medicine.* 39:173–8, 2010.
3. Agrawal Y., E.A. Platz, J.K. Niparko. ''Prevalence of Hearing Loss and Differences by Demographic Characteristics Among US Adults.'' *Archives of Internal Medicine.* 168(14):1522–30, 2008.
4. Cruickshanks K.J., T.L. Wiley, T.S. Tweed, et al., ''Prevalence of Hearing Loss in Older Adults in Beaver Dam, Wisconsin.'' *American Journal of Epidemiology.* 148(9):879–86, 1998.
5. Lin FR, R. Thorpe, S. Gordon-Salant, L. Ferrucci. ''Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States.'' *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 66A(5):582–90, 2011.
6. Garstecki DC, S.F. Erler. ''Hearing Loss, Control, and Demographic Factors Influencing Hearing Aid Use Among Older Adults.'' *Journal of Speech, Language, and Hearing Research.* 41:527–37, 1998.
7. Gates G.A., J.C. Cooper. ''Incidence of Hearing Decline in the Elderly.'' *Acta Oto-laryngol.* 111:240–8, 1991.
8. Humes L.E. ''Speech Understanding in the Elderly.'' *Journal of the American Academy of Audiology.* 7:161–7, 1996.
9. U.S. Food and Drug Administration. Code of Federal Regulations. Prescription drug advertisements, 21 CFR Sect. 202.1. 2013. (*http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=202.1)*
10. Wingfield A., L.W. Poon, L. Lombardi, D. Lowe. ''Speed of Processing in Normal Aging: Effects of Speech Rate, Linguistic Structure, and Processing Time.'' *The Journals of Gerontology.* 40(5):579–85, 1985.
11. Kramer A.F., S. Hahn, D. Gopher. ''Task Coordination and Aging: Explorations of Executive Control Processes in the Task Switching Paradigm.'' *Acta Psychologica.* 101:339–78, 1999.
12. Naveh-Benjamin M., J. Guez, A. Kilb, S. Reedy. ''The Associative Memory Deficit of Older Adults: Further Support Using Face-Name Associations.'' *Psychology and Aging.* 19(3):541–6, 2004.
13. Sommers M.S., N. Tye-Murray, B. Spehar. ''Auditory-Visual Speech Perception and Auditory-Visual Enhancement in Normal-Hearing Younger and Older Adults.'' *Ear and Hearing.* 26(3):263–75, 2005.
14. Watson J.M., K.B. McDermott, D.A. Balota. ''Attempting to Avoid False Memories in the Deese/Roediger-McDermott Paradigm: Assessing the Combined Influence of Practice and Warnings in Young and Old Adults.'' *Memory and Cognition.* 32(1):135–41, 2004.
15. Gates G.A., M.P. Feeney, D. Mills. ''Cross-Sectional Age-Changes of Hearing in the Elderly.'' *Ear and Hearing.* 29(6):865–74, 2008.
16. Morrell C.H., S. Gordon-Salant, J.D. Pearson, L.J. Brant, J.L. Fozard. ''Age- and Gender-Specific Reference Ranges for Hearing Level and Longitudinal Changes in Hearing Level.'' *Journal of the Acoustical Society of America.* 100(4)Pt. 1:1949–67, 1996.
17. Cutler A., D. Dahan, W. van Donselaar. ''Prosody in the Comprehension of Spoken Language: A Literature Review.'' *Language and Speech.* 40(2):141–201, 1997.

Dated: December 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32251 Filed 12–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0873]

Agency Information Collection Activities: Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Agency Information Collection Activities: Proposed Collection; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products'' that appeared in the **Federal Register** of December 15, 2015 (80 FR 77637). The document solicited comments on the bar code label requirements for human drug and biological products. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3330, Silver Spring, MD 20993–0002, 301–796–9115.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Tuesday, December 15, 2015, in FR Doc. 2015–31402, the following correction is made:

1. On page 77637, in the second column, the docket number is corrected to read FDA–2012–N–0873.

Dated: December 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–32252 Filed 12–22–15; 8:45 am]

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