Therefore, the estimated annual reporting burden for this information is 25,000 hours and the estimated annual recordkeeping burden is 100,000 hours.

Dated: June 22, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–15638 Filed 6–24–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2015–N–2163]**

### Agency Information Collection Activities; Proposed Collection; 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 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, ''Hearing, Aging, and Direct-to-Consumer Television Advertisements''. This study will examine how changes to hearing across the lifespan affect 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 August 24, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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:** 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.

**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 (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 (Ref. 3, 4, and 5) and, depending on their severity, influence the understanding of speech. 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; older adults are not able to hear higher frequencies as well (Ref. 7 and 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 must 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 many 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, 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 (60–75 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 (Ref. 11, 12, 13, and 14). 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 (Ref. 15 and 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.

*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?

*Design*

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

TABLE 1—PROPOSED RESEARCH DESIGN

| 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 (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 procedures and 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 prior 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.

Within each age group, participants will be randomly assigned to one of eight experimental conditions in a 2 (speed) × 2 (frequency) × 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 60 minutes.

Questionnaire measures are designed to assess, for 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.

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Pretesting: Number to Complete the Screener (Assumes 50% Eligible). | 1,280 | 1 | 1,280 | 0.08 (5 minutes) | 102.4 |

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| | | | | | |
|---|---|---|---|---|---|
| Number of Completes | 640 | 1 | 640 | 1 | 640 |
| **Main Study** | | | | | |
| Number to Complete the Screener (Assumes 50% Eligible). | 2,112 | 1 | 2,112 | 0.08 (5 minutes) | 169 |
| Number of Completes | 1,056 | 1 | 1,056 | 1 | 1,056 |
| Total | | | | | 1,967.40 |

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

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

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Dated: *June 18, 2015.*

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–D–0248]**

### Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Allowable Excess Volume and Labeled Vial Fill Size in Injectable Drug and Biological Products.'' It replaces the draft of the same name that was published on March 14, 2014. This guidance clarifies FDA requirements and regulations pertaining to allowable excess volume in injectable vials and reinforces the importance of appropriate fill volumes and labeled vial fill sizes for injectable drug and biological products.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Pallavi Nithyanandan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD