policies to assist victims of human trafficking.

Respondents: Individual participants in TVAP projects.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for Information	1250	1	.25	312.5

Estimated Total Annual Burden Hours: 312.5.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–12591 Filed 5–22–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1819]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer Prescription Drug 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: Fax written comments on the collection of information by June 25, 2015.

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 ''Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer (DTC) Prescription Drug 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Spousal Influence on Consumer Understanding of and Response to Direct-to-Consumer Prescription Drug Advertisements—(OMB Control Number 0910–NEW)

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.

Consumers are often thought of as individual targets for prescription drug advertisements (ads), as if they are always exposed to DTC ads individually and subsequently make judgments about advertised products on their own. However, judgments about prescription drugs portrayed in DTC television ads are likely made in social contexts much of the time. For example, a potential consumer and his or her spouse (*e.g.,* marital or domestic partner) may view an ad together and discuss drug benefits, side effects, and risks. These social interactions may result in unique reactions relative to consumers who view DTC prescription drug television ads alone. For example, spouses may influence their partner by expressing concern about risks and side effects that might occur, or pressuring their partner to consider the drug despite its risks and side effects. These outcomes have important public health implications. The Office of Prescription Drug Promotion plans to examine differences between consumers viewing prescription drug ads with a spouse versus alone through empirical research.

The main study will be preceded by pretesting designed to delineate the procedures and measures used in the main study. Pretest and main study participants will be couples who are married or in a marital-like living arrangement in which one member (consumer) has asthma and the other does not (spouse). All participants will be 18 years of age or older and married or cohabiting for 6 months or longer. We will exclude individuals who work in

healthcare or marketing settings because their knowledge and experiences may not reflect those of the average consumer. Data collection will take place in person.

Participants will be randomly assigned to one of four experimental conditions in a 2 x 2 design, as depicted in Table 1. We will compare one version of an ad that depicts a low benefit and low risk drug with a second version that depicts a high benefit and high risk drug. Participants will be randomly assigned to view the ad alone or together with their spouse. Participants in both viewing conditions will individually complete a prequestionnaire. In the ''together'' condition, participants will view the ad with their spouse and then engage in a brief discussion together about the ad. In the ''alone'' condition, participants will view the ad without their spouse, take a short break, and then respond to a postquestionnaire consisting of questions about information in the ad. The short break in the ''alone'' condition will facilitate reflection about the ad to mirror discussion engaged in by those in the ''together'' condition. The consumer in the ''together'' condition will complete the same postquestionnaire administered to those in the ''alone'' condition, and the spouse will complete a slightly different questionnaire that assesses key measures that relate to consumer reactions. These procedures are depicted in Table 2. Participation is estimated to take approximately 60 minutes.

Measures are designed to assess memory and understanding of risk and benefit information as well as other ad content, intention to seek more information about the product, and variables pertaining to the consumer-spouse relationship such as relationship closeness and communication style. The questionnaire is available upon request.

TABLE 1—EXPERIMENTAL STUDY DESIGN

Viewing condition	Risk/benefit condition	
	Low risk/low benefit	High risk/high benefit
Alone	Condition A ..	Condition B
Together	Condition C ..	Condition D

TABLE 2—OVERVIEW OF DATA COLLECTION PROCESS FOR ALONE AND TOGETHER CONDITIONS

Steps	Viewing condition	
	Alone	Together
1	Consumer completes prequestionnaire	Consumer and spouse complete prequestionnaire separately (spouse completes selected measures).
2	Consumer views advertising stimuli alone	Consumer and spouse view advertising stimuli together.
3	5 minute break	Couples engage in a 5 minute semi-structured conversation related to the advertising stimuli.
4	Consumer completes postquestionnaire	Consumer and spouse complete postquestionnaire separately (spouse completes selected measures).

In the **Federal Register** of November 14, 2014 (79 FR 68278), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received comments from two organizations in response to our **Federal Register** notice. In the following section, we outline the observations and suggestions raised in the comments and provide our responses.

(Comment from Abbvie) It is difficult to ascertain how the Agency will utilize the results of this study should it demonstrate that the perception of ads differs when viewed alone or with someone else. Regulating companion versus solitary viewing practices would present insurmountable legal and practical hurdles. Rather than conduct this study, we suggest that FDA resources and tax payer dollars would be better directed to research that enhances the quality of how we communicate benefit and risk information to consumers regardless of the setting in which the ad is viewed.

(Response) Much research in the social sciences demonstrates the strong influence of environmental and social conditions under which humans think and act. In regard to prescription drug advertising, it may be that when a risk is perceived as particularly negative, viewing with a partner reinforces this perception. Conversely, it may be that partners downplay risks or emphasize benefits, leading to alternate perceptions and intentions. These potential outcomes have implications for public health. Thus, it is important to generate insight about not only the message portrayed in DTC TV ads but also the conditions under which these messages are received and processed. Pending findings from this research, organizations involved in developing DTC drug communications may be encouraged to remain aware of the social context in which DTC ads are often viewed and the influence of this context on consumer perceptions, judgments, and decisions. Consideration of this broader context may facilitate the development of better DTC drug communications that remain accurate and balanced regardless of setting.

(Comment from Eli Lilly) Compelling a discussion between the consumer and spouse about the advertisement is likely to generate data that may or may not be applicable in a real-world setting. Consider removing the prescribed interaction and allow a discussion to occur if the couple so chooses.

(Response) Allowing a discussion to occur if the couple chooses could confound the research design and undermine our ability to make conclusive statements. Implementing the procedures systematically across the sample is a stronger study design (Ref. 1). There is a long tradition in the social and behavioral sciences of studying marital communication as proposed (Ref. 2). This research tradition continues because this method is more objective than participant self-reports (Ref. 3). Also, measures taken from these spousal communications are linked with important real world outcomes including health behavior and well-being (Ref. 4, Ref. 5), divorce, and marital satisfaction (Ref. 6, Ref. 2). This research method compels a discussion between partners as a way to understand the content and style of their communication. Thus, our proposed study is in keeping with the methods in this research area.

(Comment from Eli Lilly) We are challenged to understand how this research yields any useful, actionable information when it is impractical to

influence who is watching TV advertisements at any given time.

(Response) As stated in response to a previous comment, it is important to generate insight about not only the message portrayed in DTC TV ads but also the conditions under which these messages are received and processed. Such insight may facilitate the development of better DTC drug communications regardless of setting.

(Comment from Eli Lilly) Include a ''General Population'' control group.

(Response) Researching each medical condition, or general population sample, requires significant resources. We are interested in response to the ads among consumers for whom the ad is personally relevant (*i.e.,* they or their partner have been diagnosed with asthma). We are committed to conducting this research using our available resources while ensuring the integrity of the research by collecting data on a high prevalence condition for which participants might be thought of as sufficiently representative of the average consumer, thus allowing us to draw conclusions about broad perceptual and cognitive processing outcomes.

(Comment from Eli Lilly) Q12 invites speculation from respondents who may be unable to evaluate what is or is not a ''serious'' side effect. Consider eliminating this question or re-phrasing to: ''Please rate the seriousness of the side effects for [Drug X] that you remember from the ad.''

(Response) We have conducted cognitive interviews to refine and improve the survey questions. Through this process, we found that a number of participants had difficulty reading and/or answering Q12 in its original form. We also tested an alternative version of this question that conforms to the reviewer's re-phrasing, ''In your opinion, how serious are the side effects of [Drug X]?'' Many cognitive interview participants preferred this alternative version, and we will adopt it for the final questionnaire.

(Comment from Eli Lilly) Response options in Q16 may be interpreted qualitatively (*i.e.,* on the whole, the risks outweigh the benefits) or literally (*i.e.,* how many more risks were stated than benefits). Rephrasing to reflect true intent is recommended.

(Response) We appreciate this comment. This item was tested in a rigorous cognitive interview protocol and there was no indication that participants had difficulty interpreting the response options. However, we will also be conducting pretesting which will provide an additional opportunity to identify and remove questions that do not function as intended, further refining the questionnaire prior to the main study.

(Comment from Eli Lilly) Q19b is ambiguous and unclear. Rephrasing or deletion is recommended.

(Response) We tested this item as part of our cognitive interview protocol. The majority of participants understood this question, and their answers suggest that the question did a good job of distinguishing between those who focused on the arguments and facts presented in the ad versus those who paid more attention to peripheral cues, such as the visual narrative. Because the item functioned as intended, we intend to retain Q19b.

(Comment from Eli Lilly) Q20 is ambiguous and unclear. Rephrasing or deletion is recommended.

(Response) In our cognitive interviews, some participants had difficulty understanding the meaning of the introductory phrase ''In these thoughts''. Due to the ambiguity of Q20 as a whole, we will remove this item from the questionnaire.

(Comment from Eli Lilly) Q21 instructions could bias respondents to evaluate each statement as risk-related. Consider rephrasing to, ''The following statements describe how people deal with various situations.''

(Response) The Q21 battery is a validated scale specifically designed to measure attitudes toward risk (Ref. 7). Respondents are meant to evaluate the statements as though they are risk-related. Therefore, we will retain the Q21 battery.

(Comment from Eli Lilly) The scale for Q25 should be made consistent with other scales to ensure internal consistency. A scale with a midpoint is recommended.

(Response) When developing the questionnaires, we included a number of questions from existing multi-items scales. The number and format of response options differed from scale to scale (*e.g.,* 6-points vs. 10-points, fully labelled vs. anchors-only, etc.). We will revise the Likert-type response scales so that the number of levels and labeling formats across questions is consistent.

To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. With the sample size described in Table 3, 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 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pretesting					
Number to Complete the Screener	700	1	700	0.08 (5 minutes)	56
Number of Completes	120	1	120	1	120
Main Study					
Number to Complete the Screener	4,060	1	4,060	0.08 (5 minutes)	325
Number of Completes	792	1	792	1	792
Total					1,293

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

References

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.* (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any

subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Reis, H., and C. Judd, *Handbook of Research Methods in Social and Personality Psychology,* 2nd Ed. New York: Cambridge University Press (2014).

Kerig, P.K., and D.H. Baucom, (Eds.). *Couple Observational Coding Systems,* Mahwah, NJ: Erlbaum (2004).

Bakeman, R., Behavioral Observation and Coding, In H.T. Reis & C.M. Judd (Eds.) *Handbook of Research Methods in Social and Personality Psychology,*pp. 138–159. New York: Cambridge University Press (2000).

Ewart, C.K., C.B. Taylor, H.C. Kraemer, and W.S. Agras. ''High Blood Pressure and Marital Discord: Not Being Nasty Matters More Than Being Nice,'' *Health Psychology,* 10, pp. 155–163 (1991).

Spitzberg, B.H., and W.R. Cupach, *Handbook of Interpersonal Competence Research,* NY: Springer-Verlag (1989).

Gottman, J.M., *What Predicts Divorce? The Relationship Between Marital Processes and Marital Outcomes.* Hillsdale, NJ: Erlbaum (1994).

Rohrmann, B., ''Risk Attitude Scales: Concepts, Questionnaires, Utilizations [Project Report],'' University of Melbourne, Australia. Retrieved from *http://www.rohrmannresearch.net/pdfs/rohrmann-racreport.pdf* (2005).

Dated: May 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12582 Filed 5–22–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: HHS Approval of Entities That Certify Medical Review Officers (MRO).

SUMMARY: The current version of the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines), effective on October 1, 2010, addresses the role and qualifications of Medical Review Officers (MROs) and HHS approval of entities that certify MROs.

Subpart M—Medical Review Officer (MRO), Section 13.1(b) of the Mandatory Guidelines, ''Who may serve as an MRO?'' states as follows: ''Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the **Federal Register** of those entities and boards that have been approved.''

HHS has completed its review of entities that certify MROs, in accordance with requests submitted by such entities to HHS.

The HHS Secretary approves the following MRO certifying entities that offer MRO certification through examination:

American Association of Medical Review Officers (AAMRO), P.O. Box 12873, Research Triangle Park, NC 27709; Phone: (800) 489–1839; Fax: (919) 490–1010; Email: *cferrell@aamro.com*; Web site: *http://www.aamro.com/*.

Medical Review Officer Certification Council (MROCC), 836 Arlington Heights Road, #327, Elk Grove Village, IL 60007; Phone: (847) 631–0599; Fax: (847) 483–1282; Email: *mrocc@mrocc.org*; Web site: *http://www.mrocc.org/*.

DATES: HHS approval is effective May 26, 2015.

FOR FURTHER INFORMATION CONTACT: Jennifer Fan, Pharm.D., J.D., Division of Workplace Programs (DWP), Center for Substance Abuse Prevention (CSAP), Substance Abuse and Mental Health Services Administration (SAMHSA), 1 Choke Cherry Road, Room 7–1038, Rockville, MD 20857; Telephone: (240) 276–1759; Email: *jennifer.fan@samhsa.hhs.gov*

Dated: May 15, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–12559 Filed 5–22–15; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Initial Review Group; Training and Workforce Development Subcommittee—C.

Date: June 8, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Mona R. Trempe, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12A, Bethesda, MD 20892–4874, 301–594–3998, *trempemo@mail.nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: May 19, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12543 Filed 5–22–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Autologous Tumor Infiltrating Lymphocyte Adoptive Cells for the Treatment of Lung, Breast, Bladder, and HPV-Positive Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to the current licensee, Lion Biotechnologies, Inc., which is located in Woodland Hills, California to practice the inventions embodied in the following patent applications and applications claiming priority to these applications: