DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4487]

Agency Information Collection Activities; Proposed Collection; Comment Request; Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion

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, ''Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by March 6, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–4487 for ''Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A12M, 11601 Landsdown St., North Bethesda, MD 20852, *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.

Consumer and Healthcare Professional Identification of and Responses to Deceptive Prescription Drug Promotion—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.

Prescription drug promotion sometimes includes false or misleading (*i.e.,* deceptive [1]) claims, images, or other presentations; for instance, representations that a drug is more effective or less risky than is demonstrated by appropriate evidence. A number of empirical studies have examined the occurrence and influence of deceptive promotion, both in regard to prescription drugs (Ref. 1 and 2) and other products (Ref. 3 and 4). No research to our knowledge, however, has investigated the ability of consumers and healthcare professionals (HCPs) to independently identify deceptive prescription drug promotion. The ability to identify such promotion has important public health implications. If unable to identify deceptive promotion, consumers may ask their HCPs to prescribe specific drugs that they would not otherwise request. Likewise, HCPs unable to identify deceptive promotion may prescribe specific drugs that they would not otherwise prescribe. In the case that consumers and HCPs are able to identify deceptive promotion, then they may instead be equipped to incorporate such information into their medication decisions, and perhaps even report deceptive promotion to appropriate government regulators who can take corrective action. The FDA Bad Ad program, for example, encourages HCPs to report deceptive prescription drug promotion (Ref. 5), a goal which requires that HCPs successfully identify such promotion when it appears in the course of their duties. Likewise, similar programs could be implemented for consumers to report deceptive prescription drug promotion to FDA. Reports of deceptive promotion are useful to FDA because they allow investigators to focus their efforts in an era where the amount of promotion far exceeds the resources available to monitor everything.

The proposed project involves two studies examining participants' ability to detect and report deceptive (*i.e.,* false or misleading) presentations in prescription drug promotion. The studies will be conducted concurrently and will focus on different health conditions. Each study will be administered to two separate populations (*i.e.,* HCPs and consumers affected by the condition). HCPs will view mock pharmaceutical Web sites targeted toward physicians and consumers will view mock consumer-targeted pharmaceutical Web sites. The goal will be to keep the HCP and consumer-targeted Web sites as similar as possible, but to include content that is appropriate for the target audience. For example, HCP Web sites may contain more statistical information or medical terminology. A professional firm will create all mock Web sites such that they are indistinguishable from currently available prescription drug Web sites.

Study 1 and 2 Sample. Study 1 will sample consumers diagnosed with chronic pain that has lasted at least 3 months. Chronic pain has an incidence rate of roughly 11 percent (Ref. 6). Study 2 will sample consumers diagnosed with obesity, defined as body mass index greater than or equal to 30 (35 percent incidence; Ref. 7). The HCP samples for both studies will include physicians whose primary medical specialty is either primary care or internal medicine and whose responsibilities involve direct patient care at least 50 percent of the time. For both consumers and HCPs, pretest participants will not be eligible for the main study.

Pretesting. Pretesting will take place before the main studies to evaluate the procedures and measures used in the main studies. Each of the two pretests will have the same design as its respective main study (pretest 1 for Study 1 and pretest 2 for Study 2). The purpose of both pretests will be to: (1) Ensure that the mock Web sites are understandable, viewable, and delivering intended messages; (2) identify and eliminate any challenges to embedding the mock Web sites within the online survey; (3) ensure that survey questions are appropriate and meet the analytical goals of the research; and (4) pilot test the methods, including examining response rates and timing of survey. The two pretests will be conducted simultaneously. Based on pretest findings, we will refine the mock Web sites, survey questions, and data collection process, as necessary, to optimize the full-scale study conditions.

Main Studies. The proposed design for the main studies, including sample sizes, is summarized below and described next.

STUDY 1—DEGREE OF DECEPTION BASED ON THE NUMBER OF DECEPTIVE CLAIMS

Population	Experimental condition			
	None (control)	Fewer violations	More violations	Total
HCPs	125	125	125	375
Consumers w/chronic pain	125	125	125	375

STUDY 2—TYPE OF DECEPTION BASED ON IMPLICIT AND EXPLICIT CLAIMS

Population	Experimental condition			
	None (control)	Implicit	Explicit	Total
HCPs	125	125	125	375
Obese consumers	125	125	125	375

[1] Our use of the term *deceptive* is not meant to imply equivalence (or lack thereof) with use of the same term by the U.S. Federal Trade Commission. As defined in this document, we use this term to refer to presentations that are considered false or misleading within the context of prescription drug promotion.

The purpose of Study 1 is to assess consumer and HCP response to promotional Web sites with varying levels of false or misleading presentations. In Study 1, degree of deception will be manipulated over three levels by altering the number of deceptive claims (none, fewer, more). It is possible that consumers and HCPs are only able to identify ads as deceptive when they include a greater number of violations, whereas ads with few violations may not be identified as deceptive. The experimental stimuli will be in the form of a Web page for a fictitious drug targeted toward consumers who have chronic pain or toward HCPs. The deceptive Web sites will contain various types of violations. The Web site with fewer violations will contain a subset of the deceptive claims, imagery, or other presentations included in the Web site with more violations. For example, if the fewer-violations Web site includes two violations, then the more-violations Web site will include the same two violations plus two or three additional violations (in the form of claims and/or graphics).

Study 1 will help FDA address several key questions:

- What proportion of consumers and HCPs correctly identify a promotional piece as deceptive? Does the ability to identify deceptive promotion vary depending on the number of deceptive claims in a promotional piece?
- Does the degree of deception affect consumers' and HCPs' attitudes and behavioral intentions toward the promoted drug, including intended reporting to regulatory authorities?
- Is the effect of deceptive promotional pieces mediated by a person's ability to identify a promotional piece as deceptive (that is, do people who recognize a piece as deceptive discount the information in the piece, thereby adjusting their attitudes and intentions toward the product)?

Whereas Study 1 focused on the *level* of deception (based solely on the number of false or misleading claims), Study 2 focuses on the *type* of deception (implicit versus explicit). Many deceptive promotional claims are implicit rather than being explicitly false (Ref. 1 and 4). An implicit claim suggests or implies an unstated piece of information. An explicit claim fully and clearly expresses information and leaves nothing to be implied. Study 2 will compare perceptions and beliefs that consumers and HCPs hold about a drug following exposure to one of three versions of a prescription drug Web site: (1) An explicitly false Web site, (2) a factually true but implicitly misleading Web site, or (3) a Web site with no deceptive claims (the control group).

As with Study 1, we envision a pair of one-way factorial experiments, one conducted with a sample of consumers and the other with HCPs. Similar to Study 1, Study 2 will investigate how misleading implicit claims and explicitly false claims in prescription drug promotional pieces influence a person's ability to detect and respond appropriately to deception. The experimental stimuli will be in the form of a mockup of a pharmaceutical Web site targeted toward the relevant experimental population, obese consumers or HCPs who treat obese patients. The drug profile, including indication, risks, and logo branding will be fictitious. For the implicit misleading claim manipulations, we are interested in whether people infer false beliefs from the implicit communications.

Study 2 will help FDA address several key questions:

- What proportion of consumers and HCPs correctly identify a promotional piece as deceptive? Does the ability to identify deceptive promotion vary depending on whether deceptive claims in a promotional piece are explicit versus implicit?
- Does the type of deception affect consumers' and HCPs' attitudes and behavioral intentions toward the promoted drug, including intended reporting to regulatory authorities?
- Is the effect of deceptive promotional pieces mediated by a person's ability to identify a promotional piece as deceptive (that is, do people who recognize a piece as deceptive discount the information in the piece, thereby adjusting their attitudes and intentions toward the product)?

Measurement. Identifying how to measure consumers' and HCPs' ability to identify deceptive promotion as well as their reaction to such promotion is fundamental to achieving the research goals. A literature review revealed the importance of using a variety of measures to capture detection of deception. For direct measures, we will incorporate questions that ask participants to indicate whether there was any deception in the promotional piece and to rate the promotional piece in terms of how deceptive, credible, or trustworthy it was. Additionally, we will include claim-specific direct measures that allow people to click on any part of the Web site that they deem deceptive. Using responses to this variable, we can assess whether participants think there is any deception in a promotional piece; in instances where they do think there is deception, we can assess what aspects of the Web site contributed to that belief. We will also include indirect measures that identify whether participants believed the Web site expressed particular claims (*e.g.,* claim recognition) as well as participants' beliefs about the veracity of any deceptive claims (*e.g.,* claim truth, agreement, or acceptance). Moreover, we will assess whether participants believe the messages merit reporting to regulatory authorities (that is, FDA). To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance. A copy of the draft questionnaire is available upon request.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pilot study screener completes	4,286 (chronic pain) 714 (obesity) 612 (HCP)	1	5,612	0.03 (2 minutes)	187
	5,612 total				
Main study screener completes	10,714 (chronic pain) 1,786 (obesity) 1,531 (HCP)	1	14,031	0.03 (2 minutes)	468

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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	14,031 total				
Pilot study completes	150 (chronic pain) 150 (obesity) 300 (HCP)	1	600	0.33 (20 minutes)	200
	600 total				
Main study completes	375 (chronic pain) 375 (obesity) 750 (HCP)	1	1,500	0.33 (20 minutes)	500
	1,500 total				
Total					1,355

[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 (see **ADDRESSES**) 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 *https://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. Faerber, A.E. and D.H. Kreling. ''Content Analysis of False and Misleading Claims in Television Advertising for Prescription and Nonprescription Drugs.'' *Journal of General Internal Medicine,* 2014. 29(1): 110–118.
2. Symonds, T., C. Hackford, and L. Abraham. ''A Review of FDA Warning Letters and Notices of Violation Issued for Patient-Reported Outcomes Promotional Claims Between 2006 and 2012.'' *Value in Health,* 2014. 17: 433–437.
3. Mitra, A., M.A. Raymond, and C.D. Hopkins. ''Can Consumers Recognize Misleading Advertising Content in a Media Rich Online Environment?'' *Psychology & Marketing,* 2008. 25(7): 655–674.
4. Hastak, M., and M.B. Mazis. ''Deception by Implication: A Typology of Truthful but Misleading Advertising and Labeling Claims.'' *Journal of Public Policy & Marketing,* 2011. 30(2): 157–167.
5. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, E. Geisen, et al. ''Awareness of the FDA's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings.'' *Journal of Health Communication,* 2015. 20: 1330–1336.
6. Nahin, R.L. ''Estimates of Pain Prevalence and Severity in Adults: United States, 2012.'' *Journal of Pain,* 2015. 16(8): 769–780.
7. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics (2015). ''Healthy Weight, Overweight, and Obesity Among Adults Aged 20 and Over, By Selected Characteristics: United States, Selected Years 1988–1994 hrough 2009–2012 [Table].'' In *Health, United States, 2014* with special feature on adults aged 55–64 (pp. 214–220; DHHS Publication No. 2015–1232). Retrieved from *http://www.cdc.gov/nchs/data/hus/hus14.pdf.*

Dated: December 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31845 Filed 1–3–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Biochemistry and Biophysics of Membranes Study Section.

Date: January 31, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Synthetic and Biological Chemistry A Study Section.

Date: January 31–February 1, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel, 1700 Tysons Boulevard, McLean, VA 22102.

Contact Person: Anita Szajek, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4187, Bethesda, MD 20892, 301–827–6276, *anita.szajek@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–14–264 Global Omics Approaches Targeting Adverse Pregnancy and Neonatal Outcomes Utilizing Existing Cohorts.

Date: January 31, 2017.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301–594–6594, *steeleln@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844,