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 screener	120	1	120	0.03 (2 minutes)	4
Study 1 screener	600	1	600	0.03 (2 minutes)	18
Study 2 screener	600	1	600	0.03 (2 minutes)	18
Completes, Pilot	40	1	40	1	40
Completes, Study 1	200	1	200	1	200
Completes, Study 2	200	1	200	1	200
Total					480

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

II. References

The following references are on display in the Dockets Management Staff (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. McGuire, L.C., ''Remembering What the Doctor Said: Organization and Older Adults' Memory for Medical Information.'' *Experimental Aging Research,* 22, 403–428 (1996).
2. Aikin, K.J., J.L. Swasy, and A.C. Braman, ''Patient and Physician Attitudes and Behaviors Associated with DTC Promotion of Prescription Drugs: Summary of FDA Survey Research Results'' (2004). Available at *http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/UCM152860.pdf.*
3. Warnings and Risk Communication (2005). Wogalter, M.S., D. DeJoy, and K.R. Laughery (Eds.). Philadelphia: Taylor & Francis, Inc.
4. Conzola, V.C., and M.S. Wogalter, ''A Communication-Human Information Processing (C–HIP) Approach to Warning Effectiveness in the Workplace.'' *Journal of Risk Research,* 4(4), 309–322; (2001).
5. Wogalter, M.S., and K.R Laughery, ''Warning! Sign and Label Effectiveness.'' *Current Directions in Psychological Science,* 5(2), 33–37; (1996).
6. Wogalter, M.S., T.L. Smith-Jackson, B.J. Mills, and C.S. Paine, ''The Effects of Print Format in Direct-to-Consumer Prescription Drug Advertisements on Risk Knowledge and Preference.'' *Drug Information Journal,* 36(3), 693–705, 2002.

Dated: June 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12600 Filed 6–16–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1779]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 ''Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion.''

DATES: Submit either electronic or written comments on the collection of information by August 18, 2017.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2017–N–1779 for ''Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 Dockets Management Staff. 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.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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.

Disclosures of Descriptive Presentations in Professional Oncology 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 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.

Under the FD&C Act and implementing regulations, promotional labeling and advertising about prescription drugs are generally required to be truthful, non-misleading, and to reveal facts material to the presentations made about the product being promoted (see sections 502(a) and (n), and 201(n) of the FD&C Act (21 U.S.C. 352(a) and (n), and 321(n)); see also 21 CFR 202.1). As a part of the ongoing evaluation of FDA's regulations in this area, FDA is proposing to study the impact of disclosures as they relate to presentations of preliminary or descriptive scientific and clinical data in promotional labeling and advertising for oncology products. The use of disclosures is one method of communicating information to health care professionals about scientific and clinical data, the limitations of that data, and practical utility of that information for use in treatment. These disclosures may influence prescriber comprehension and decisionmaking, and may affect how and what treatment they prescribe for their patients.

Pharmaceutical companies market directly to physicians through publishing advertisements in medical journals, exhibit booths at physician meetings or events, sending unsolicited promotional materials to doctors' offices, or presentations (''detailing'') by pharmaceutical representatives (Ref. 1). Detail aids may contain carefully extracted data from clinical studies that, taken out of context, can exaggerate the benefits of a drug (Ref. 2) or contribute to physicians prescribing the drug for an inappropriate patient population.

Promotional labeling and advertising for cancer drugs deserve specific attention. Oncology drugs represented 26 percent of the 649 compounds under clinical trial investigation from 2006 to 2011 (Ref. 3). The past decade has seen a dramatic rise in the number of oncology drugs brought to market. In the past 18 months, FDA has approved 27 cancer drugs (Ref. 4). Although overall survival remains the gold standard for demonstrating clinical benefit of a drug, several additional endpoints are accepted as surrogates illustrating clinical benefit with regard to cancer and many drugs are granted expedited approval on their basis. These include disease-free survival, objective response rate, complete response rate, progression-free survival, and time to progression (Ref. 5). For clinicians who are not specifically trained in clinical trial design, interpreting these endpoints may be challenging. Pharmaceutical companies invest heavily in the development and distribution of promotional materials to educate oncologists about favorable clinical trial results.

When communicating scientific and clinical data, a disclosure (a specific statement that modifies or qualifies a claim) could be used to convey the limitations of the data and practical

utility of the information for treatment. Much of the prior research on disclosures in this topic area has been limited to the dietary supplement arena with consumers (Refs. 6–9). Disclosures in professional pieces could influence prescriber comprehension as well as subsequent decisionmaking; however, no published data exist regarding how prescribers use and understand scientific claims in conjunction with qualifying disclosures.

Different aspects of disclosures may influence their effectiveness. For example, despite the advanced education of health care providers, in a busy practice they may not be willing or able to process the disclosures thoroughly. Thus, the level of technicality in the disclosure may play a role in their use of the disclosure to contextualize the data display. Additionally, the addition of a general summary statement to frame the disclosure may help or hinder the processing of the disclosure and therefore the entire data display. Finally, it is possible that the impact of disclosure statements on prescriber comprehension, perceptions, and intentions to prescribe the promoted product will vary based on the level of clinical training. Although oncologists and primary care physicians (PCPs) will have more experience with clinical data, mid-level practitioners have reported having significantly more formal training on pharmaceutical marketing tactics than specialists and PCPs (Ref. 10). Therefore, it is unclear whether any one group would be more or less affected by both the claims made in promotional materials or by the disclosures that accompany those claims.

The proposed study seeks to address the following research questions:

1. Do disclosures mitigate potentially misleading presentations of preliminary or descriptive data in oncology drug product promotion?

2. Does the language (technical, non-technical) of the disclosure influence the effectiveness of the disclosure?

3. Does the presence of a general statement about the clinical utility of the data in addition to a specific disclosure influence processing of claims and disclosures?

4. Do PCPs, oncologists, and mid-level practitioners (nurse practitioners, physician assistants) differ in their processing of claims and disclosures about preliminary or descriptive data?

5. Which disclosures do physicians prefer?

To address these questions, FDA has designed a study that will be conducted in three independent phases, each phase examining a data display in a promotional piece for a unique oncological product. Independent variables will include: (1) Specific disclosure (technical, non-technical, none), (2) general statement (present, absent), and (3) specialty (oncologists, PCPs, mid-level practitioners). Each phase will have the following design:

Sample	General statement	Specific disclosure		
		Technical	Non-technical	No disclosure
Oncologists	Present	•	•	Control.
	Absent	•	•	
PCPs	Present	•	•	Control.
	Absent	•	•	
Mid-Level Practitioners	Present	•	•	Control.
	Absent	•	•	

Specific disclosures will include material information specifically related to the particular data display in question. As such, each specific disclosure may include clinical or statistical information related to the trial design, the statistical analysis plan of the trial, or any other material statistical or clinical information necessary for evaluation or interpretation of the data. The team developing the disclosures includes social science analysts, pharmacists, oncological medical officers, and an oncology nurse. An example of the general statement is ''This presentation includes exploratory information of uncertain clinical utility and should be interpreted cautiously when used to make treatment decisions.''

Outcome variables will focus on the assessment of the data display as a whole as well as attention to the disclosure, if present. Specifically, we will examine recognition of the clinical endpoint in the data display, comprehension of the data display, perceptions of the exploratory nature of the data, and the perceived credibility of the promotional piece. We will also look at attention to the specific disclosure and the general statement, prescriber decisions, and prescriber preferences. This latter outcome variable will be determined by a secondary task at the end of the questionnaire that shows each participant all disclosure options and asks them to choose their preferred version.

Oncologists, PCPs, and non-oncology mid-level practitioners will be recruited to participate via the Internet, and the study is expected to take approximately 20 minutes. Participants will view professionally developed promotional pieces that mimic currently available promotion and answer questions. The 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 [2]
Pretest Screener	134	1	134	0.03 (2 minutes)	5
Pretest	90	1	90	0.33 (20 minutes)	30
Main Study Screener	3,134	1	3,134	0.03 (2 minutes)	105
Main Study	2,115	1	2,115	0.33 (20 minutes)	705

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 [2]
Total					845

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the next full hour.

II. References

The following references are on display in the Dockets Management Staff (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. Johar, K., ''An Insider's Perspective: Defense of the Pharmaceutical Industry's Marketing Practices,'' *Albany Law Review,* 76:299–334, 2012–2013.
2. Wick, C., M. Egger, S. Trelle, et al., ''The Characteristics of Unsolicited Clinical Oncology Literature Provided by Pharmaceutical Industry,'' *Annals of Oncology,* 18:1580–1582, 2007.
3. Fisher, J.A., M.D. Cottingham, and C.A. Kalbaugh, ''Peering Into the Pharmaceutical 'Pipeline': Investigational Drugs, Clinical Trials, and Industry Priorities,'' *Social Science & Medicine,* 131:322–330, 2015.
4. Centerwatch, ''FDA Approved Drugs for Oncology,'' *https://www.centerwatch.com/drug-information/fda-approved-drugs/therapeutic-area/12/oncology* (accessed on March 2, 2017).
5. Pazdur, R., ''Endpoints for Assessing Drug Activity in Clinical Trials,'' *The Oncologist,* 13:19–21, 2008.
6. Dodge, T. and A. Kaufman, ''What Makes Consumers Think Dietary Supplements Are Safe and Effective? The Role of Disclaimers and FDA Approval,'' *Health Psychology,* 26:513–517, 2007.
7. Dodge, T., D. Litt, and A. Kaufman, ''Influence of the Dietary Supplement Health and Education Act on Consumer Beliefs About the Safety and Effectiveness of Dietary Supplements,'' *Journal of Health Communication,* 16:230–244, 2011.
8. Mason, M.J., D.L. Scammon, and X. Fang, ''The Impact of Warnings, Disclaimers, and Product Experience on Consumers' Perceptions of Dietary Supplements,'' *The Journal of Consumer Affairs,* 41:74–99, 2007.
9. France, K.R. and P.F. Bone, ''Policy Makers' Paradigms and Evidence From Consumer Interpretations of Dietary Supplement Labels,'' *The Journal of Consumer Affairs,* 39:27–51, 2005.
10. O'Donoghue, A.C., V. Boudewyns, K.J. Aikin, et al., ''Awareness of the Food and Drug Administration's Bad Ad Program and Education Regarding Pharmaceutical Advertising: A National Survey of Prescribers in Ambulatory Care Settings,'' *Journal of Health Communication,* 20:1330–1336, 2015.

Dated: June 13, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12599 Filed 6–16–17; 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: Center for Scientific Review Special Emphasis Panel; RFA Panel: Revision Applications for U.S.-South Africa Program for Collaborative Biomedical Research.

Date: June 29, 2017.

Time: 2:00 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 (Telephone Conference Call).

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.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.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Molecular and Cellular Biology Study Section.

Date: July 10, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Kenneth A. Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; AIDS and Related Research Member Conflict.

Date: July 10, 2017.

Time: 10:00 a.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: Shalanda A. Bynum, Ph.D., MPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, Bethesda, MD 20892, 301–755–4355, *bynumsa@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 16–257: Predicting Behavioral Responses to Population Level Cancer Control Strategies (R21).

Date: July 11, 2017.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Karin F. Helmers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 254–9975, *helmersk@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 15–287: Opportunities for Collaborative Research at the NIH Clinical Center.

Date: July 11, 2017.

Time: 1:30 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: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of