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.


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叠加 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: Ilia S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@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 fair, balanced, and not misleading, and to reveal facts material to the presentations made about the product being promoted (see sections 502(a) and (n), and 301(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 seem 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 qualify 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:

<table>
<thead>
<tr>
<th>Sample</th>
<th>General statement</th>
<th>Specific disclosure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Present</td>
<td>Technical</td>
</tr>
<tr>
<td>Oncologists</td>
<td>Present</td>
<td>•</td>
</tr>
<tr>
<td>PCPs</td>
<td>Absent</td>
<td>•</td>
</tr>
<tr>
<td>Mid-Level Practitioners</td>
<td>Present</td>
<td>•</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretest Screener</td>
<td>134</td>
<td>1</td>
<td>134</td>
<td>0.03 (2 minutes)</td>
<td>5</td>
</tr>
<tr>
<td>Pretest</td>
<td>90</td>
<td>1</td>
<td>90</td>
<td>0.33 (20 minutes)</td>
<td>30</td>
</tr>
<tr>
<td>Main Study Screener</td>
<td>3,134</td>
<td>1</td>
<td>3,134</td>
<td>0.03 (2 minutes)</td>
<td>105</td>
</tr>
<tr>
<td>Main Study</td>
<td>2,115</td>
<td>1</td>
<td>2,115</td>
<td>0.33 (20 minutes)</td>
<td>705</td>
</tr>
</tbody>
</table>
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.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12599 Filed 6–16–17; 8:45 am]
BILING 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: 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: Pungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, 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 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, bynumssa@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 (Virtual Meeting).

Contact Person: Fungai Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301–435–1050, freudr@csr.nih.gov.