requests for pediatric studies, if appropriate. The product under consideration is ONC201, presentation by Oncoceutics Inc.

On page 19789, in the third column, the third sentence of the *Procedure* portion of the document is changed to read as follows:

Oral presentations from the public will be scheduled between approximately 10:50 a.m. and 11:20 a.m. and 1:50 p.m. and 2:20 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13142 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2313]

Agency Information Collection Activities; Proposed Collection; Comment Request; Study of Oncology Indications in Direct-to-Consumer Television Advertising

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 (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 ''Study of Oncology Indications in Direct-to-Consumer Television Advertising.'' This research consists of two studies examining the presentation of oncology indications in direct-to-consumer (DTC) television ads.

DATES: Submit either electronic or written comments on the collection of information by August 20, 2019.

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 20, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 20, 2019. 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–2019–N–2313 for ''Study of Oncology Indications in Direct-to-Consumer Television Advertising.'' 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: *https://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, 10 a.m.–12 p.m., 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov*. *For copies of the questionnaire contact:* Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@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.

Study of Oncology Indications in Direct-to-Consumer Television Advertising

(OMB Control Number 0910–NEW)

I. Background

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 (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.

OPDP's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about treatment options. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study falls under the topic of advertising features (content and format).

Oncology products are increasingly being promoted to consumers via DTC television advertising. Oncology indications are often complicated and supported by different clinical endpoints such as overall survival, overall response rate, and progression-free survival (Ref. 1) that are referenced in the DTC TV ads. The first objective of this project is to determine whether disclosing information about the nature of the endpoints that support the indications for oncology products helps consumers understand the drug's efficacy. This objective complements OPDP's research examining disclosing information about FDA's accelerated approval pathway to consumers (May 8, 2019, 84 FR 20148) and OPDP's research on disclosing oncology information to healthcare professionals (OMB control number 0910–0864—Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion). Although these studies all contribute to our knowledge of the communication of cancer treatment information, the current study specifically examines particular endpoints that are well-known to the professional oncology community and are now used in DTC advertising.

Because of the length of some indications, sponsors sometimes convey some of the indication in superimposed text rather than in the audio in the TV ads. The second objective is to test whether consumers adequately comprehend indication statements when portions of the indication are presented only in the superimposed text of television ads while other information is conveyed in the audio. This objective extends OPDP's previous research on the use of dual-modality *risk* presentations (presenting the information in two modes at the same time; OMB control numbers 0910–0634—Experimental Evaluation of the Impact of Distraction, 0910–0652—Experimental Study: Toll-Free Number for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer Television Advertisements for Prescription Drugs, and 0910–0772—Eye Tracking Study of Direct-to-Consumer Prescription Drug Advertisement Viewing) to the context of *indication* statements. This previous research supports the use of dual modality to increase consumers' understanding of risk information (January 27, 2012, 77 FR 4273) (Refs. 2 and 3).

We plan to conduct two rounds (one for each objective) of nine 1-hour in-person cognitive interviews of adults 18 years of age or older to refine the questionnaires and stimuli (18 participants total). We plan to conduct two pretests (one for each objective) not longer than 20 minutes, administered via internet panel, to test the experimental manipulations and pilot the main study procedures.

We plan to conduct two main studies (one for each objective) not longer than 20 minutes, administered via internet panel. For Study 1, we will create two television ads for fictitious oncology prescription drugs to increase the generalizability of the results (one solid tumor indication and one hematology indication). The ads will include audio claims about overall survival, overall response rate with and without a disclosure, or progression-free survival with and without a disclosure (see table 1 for the Study 1 design).

Some current television ads for oncology products include disclosures that are intended to help consumers differentiate surrogate endpoints like progression-free survival and overall response rate from overall survival. Examples include ''At the time of analysis, overall survival comparison was not yet available'' and ''Clinical trials are ongoing to determine if there is an overall survival benefit.'' The disclosure we use in the study will be based on disclosures currently in use and will be informed by consumer feedback elicited in focus groups conducted prior to the cognitive testing (approved under OMB control number 0910–0695). For example, the study disclosure may include language such as ''We currently do not know if Drug X helps people live longer.''

Participants will be randomly assigned to view one prescription drug television ad and then complete a questionnaire that assesses whether participants noticed the disclosure, their interpretations of the disclosure, their retention of the endpoint, and their perceptions of the drug's benefits and risks. We will also measure covariates such as demographics, cancer history,

and literacy. Without a disclosure, we hypothesize that participants will not differentiate between overall survival, overall response rate, and progression-free survival. We hypothesize that a disclosure will help participants understand the surrogate endpoints (*i.e.,* overall response rate and progression-free survival) and thus will lead to greater understanding of the drug's efficacy compared with conditions without the disclosure. We will explore unintended effects of the disclosure, such as whether the disclosure lowers perceived efficacy compared with the overall survival condition.

For the second objective, in Study 2 we will vary the presentation of the products' indication, such that material information related to the indication will appear in superimposed text only, in the audio only, in both superimposed text and audio, or in neither (the control condition; see tables 2 and 3 for the Study 2 design). Participants will be randomly assigned to view a prescription drug television ad and then complete a questionnaire that assesses their retention and comprehension of the information. Following previous research on dual-modality presentations, we hypothesize that participants who view an ad with the material information in the audio and text will have greater retention of that information than participants in any other condition. We also hypothesize that participants who view an ad with the material information in the audio only will have greater retention of that information than participants in the superimposed text condition and the control condition. To test Study 1 and 2 hypotheses, we will conduct inferential statistical tests such as logistic regression and analysis of variance.

The questionnaires are available upon request from *DTCresearch@fda.hhs.gov.*

For all phases of this research, we will recruit a general population sample of adult volunteers 18 years of age or older. We will exclude individuals who work for the Department of Health and Human Services or work in the healthcare, marketing, or pharmaceutical industries. We will use literacy quotas to ensure that our sample includes participants with a range of literacy skills. We will also exclude pretest participants from the main studies, and participants will not be able to participate in both Studies 1 and 2. With the sample sizes described below, we will have sufficient power to detect small-sized effects in Studies 1 and 2 (table 4).

TABLE 1—STUDY 1 DESIGN

Indication	Overall survival	Overall response rate	Overall response rate with disclosure	Progression-free survival	Progression-free survival with disclosure
Solid Tumor					
Hematology					

Note: The solid tumor condition will be non-small cell lung cancer. The hematology condition will be multiple myeloma. Claims and disclosures are TBD, based on focus group feedback. Overall survival and progression-free survival claims will be the same for both indications. Study 1 will use the control ad from Study 2.

TABLE 2—STUDY 2 DESIGN: SOLID TUMOR

Indication presentation			
Material information in superimposed text only	Material information in audio only	Material information in superimposed text + audio	Material information not in superimposed text or audio (control)
Audio: Drug X is for adults with advanced non-small cell lung cancer. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene.	Audio: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer.	Audio: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer previously treated with platinum-based chemotherapy, who have a certain type of ALK gene.	Audio: Drug X is for adults with advanced non-small cell lung cancer. Superimposed text: Drug X is for adults with advanced non-small cell lung cancer.

Note. Study 2 will use the overall survival ad from Study 1.

TABLE 3—STUDY 2 DESIGN: HEMATOLOGY

Indication presentation			
Material information in superimposed text only	Material information in audio only	Material information in superimposed text + audio	Material information not in superimposed text or audio (Control)
Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma in combination with dexamethasone, in people who have received at least three prior medicines to treat multiple myeloma.	Audio: Drug Y is used to treat multiple myeloma. Superimposed text: Drug Y is used to treat multiple myeloma.

Note. Study 2 will use the overall survival ad from Study 1.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive Interview screener	30	1	30	0.08 (5 minutes)	2.4
Cognitive Interviews	18	1	18	1 (60 minutes)	18
Pretests 1 and 2 screener	200	1	200	0.08 (5 minutes)	16
Pretests 1 and 2	120	1	120	0.33 (20 minutes)	39.6
Study 1 screener	1,167	1	1,167	0.08 (5 minutes)	93.36
Study 1	700	1	700	0.33 (20 minutes)	231
Study 2 screener	867	1	867	0.08 (5 minutes)	69.36
Study 2	520	1	520	0.33 (20 minutes)	171.6
Total					641.32

[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 with 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; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Kim, J., J. Gao, L. Amiri-Kordestani, et al., ''Patient-Friendly Language to Facilitate Treatment Choice for Patients with Cancer.'' The Oncologist, 10.1634/theoncologist.2018-0761, 2019. Available from: *http://theoncologist.alphamedpress.org/content/early/2019/05/16/theoncologist.2018-0761.short?rss=1*.
2. Aikin, K.J., A.C. O'Donoghue, C.M. Squire, et al., ''An Empirical Examination of the FDAAA-Mandated Toll-Free Statement for Consumer Reporting of Side Effects in Direct-to-Consumer Television Advertisements.'' *Journal of Public Policy & Marketing,* 35(1):108–123, 2016.
3. Sullivan, H.W., V. Boudewyns, A.C. O'Donoghue, et al., ''Attention to and Distraction from Risk Information in Prescription Drug Advertising: An Eye-Tracking Study.'' *Journal of Public Policy & Marketing,* 36(2):236–245, 2017.

Dated: June 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–13128 Filed 6–20–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0021]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

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 July 22, 2019.