

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 <http://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: Brian Kehoe, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8913.

SUPPLEMENTARY INFORMATION:

I. Background

Under Executive Order 13175 of November 6, 2000, executive departments and Agencies are charged with engaging in regular and meaningful consultation and collaboration with tribal officials in the development of Federal policies that have tribal implications and are responsible for strengthening the government-to-government relationship between the United States and Indian tribes. The Department of Health and Human Services (HHS) Tribal Consultation Policy, revised on December 14, 2010, further clarifies that each HHS Operating and Staff Division must have an accountable consultation process to ensure meaningful and timely input by Tribal officials in the development of policies that have Tribal implications. To date, FDA has followed the HHS Tribal Consultation Policy (available at <http://www.hhs.gov/about/agencies/iea/tribal-affairs/consultation/index.html>). The draft FDA Tribal Consultation Policy is based on the HHS Tribal Consultation Policy and includes Agency-specific consultation guidelines that complement the Department-wide efforts.

The purpose of the draft FDA Tribal Consultation Policy, when finalized, is to establish clear policies to further the government-to-government relationship between FDA and Indian Tribes and facilitate tribal consultation with FDA. The draft policy provides background on FDA's mission and organizational structure and sets out principles and guidelines for the tribal consultation process. FDA intends for its Tribal Consultation Policy to serve as a platform for the Agency to create

consistent and meaningful tribal consultation across FDA Centers and Offices.

FDA is announcing the establishment of a docket to receive comments on the draft FDA Tribal Consultation Policy. We invite tribal officials, tribal organizations, individual tribal members and other interested persons to comment on the draft FDA Tribal Consultation Policy. We are interested in any general comments or concerns that would help us improve our policy as well as suggestions on how we can improve our communication and outreach with Indian Tribes. FDA also intends to consult with Indian Tribal officials on the draft FDA Tribal Consultation Policy and summaries of these consultations will be placed in the docket.

II. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ForFederalStateandLocalOfficials/TribalAffairs/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the document.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0544]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Direct-to-Consumer Advertising Survey

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, "National Direct-to-Consumer Advertising Survey." The objective of this research is to survey the

public about their experiences with and attitudes toward direct-to-consumer (DTC) advertising of prescription drugs.

DATES: Submit either electronic or written comments on the collection of information by April 29, 2016.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-0544 for "Agency Information Collection Activities; Proposed Collection; Comment Request; National Direct-to-Consumer Advertising Survey." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://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 <http://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 <http://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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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.

National Direct-to-Consumer Advertising Survey

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.

FDA last surveyed patients about their experiences with and attitudes toward DTC advertising in 2002 (Ref. 1). Numerous changes have affected the DTC landscape since 2002, including declines in print readership, the rise in online prescription drug promotion, and self-imposed industry guidelines for DTC advertising (Ref. 2). These changes may have affected consumers’ exposure to different kinds of DTC advertising and its influence on their attitudes and behaviors. The purpose of the National Direct-to-Consumer Advertising Survey is to collect updated insights on consumer experiences with and attitudes towards DTC promotion of prescription drugs. This study will build on previous research by recruiting a wider range of respondents, weighting the data to make it nationally representative, and ask a wider range of questions about DTC promotion, including in online formats.

We plan to use an address-based mixed-mode methodology that will direct one randomly-chosen member of sampled households to complete a 20-minute online survey, with non-respondents receiving a paper questionnaire. The sample will be representative of the U.S. population. A sample of U.S. households will be drawn from the U.S. Postal Service Computerized Delivery Sequence File. Adults aged 18 or over will be eligible for participation. Up to five contacts will be sent to respondents by U.S. mail. The contacts will include the URL for the online survey and a unique personal identification number (PIN). This unique PIN will be used to track completed surveys without the use of personally identifying information. The contact method, based on recent recommendations (Ref. 3), includes a notification letter (Day 1), a reminder/thank-you postcard (Day 5), a second letter sent to nonresponders (Day 12), a paper version of the survey mailed to nonresponders (Day 19), and a reminder postcard sent to nonresponders (Day 24).

Based on previous research (Refs. 4, 5, and 6), we plan to recruit using two \$1 bills (\$2 total per sampled respondent) mailed in advance with the initial invitation letter as a gesture to encourage response and maintain data quality. Offering a small token of value to participants establishes a latent social contract and subsequent reciprocity (Ref. 3). In the second contact attempt, we will conduct an experiment to test whether a short statement mentioning the previously paid incentive increases survey response, thereby testing whether social exchange can be extended past the initial contact attempt. Half the sample will be provided language that reminds them they received a cash incentive in the previous letter; the remaining half will be reminded they received a letter but will not be specifically reminded about the incentive.

We estimate a 35 percent response rate, based on recent work on similar studies (Ref. 7). Prior to the main study, a pilot study will be conducted to test the data collection process. We estimate 35 respondents will complete the pilot study and 1,765 will complete the main study (see table 1).

The survey contains questions about respondents’ knowledge of FDA’s authority with respect to prescription drug advertising, their exposure to DTC advertising, their beliefs and attitudes about DTC advertising, and the influence of DTC advertising on further information search and patient-physician interactions. At the end of the

survey, respondents will be randomly assigned to view one of two ads for fictional prescription drugs intended to treat high cholesterol. They will be asked questions about FDA's authority regarding specific claims within the ad. The survey will include a debriefing to inform respondents that the advertised drug was fictitious. We will also measure other potentially important

characteristics such as demographics, insurance coverage, and prescription drug use. The survey is available upon request.

We will test for any differences between modes (online versus mail survey) and will account for any mode effects in our analyses. We will weigh the data to account for different probability of selection and

nonresponse. We will examine the frequencies for survey items and the relation between survey items and demographic and health characteristics. We also plan to compare responses between this survey and FDA's 2002 survey for repeated items.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|-----------------------|------------------------------------|------------------------|-----------------------------|-------------|
| Pilot Study | | | | | |
| Survey invitation letter | 100 | 1 | 100 | .08 (5 min.) | 8 |
| Reminder postcard | 100 | 1 | 100 | .03 (2 min.) | 3 |
| Non-response letter | 82 | 1 | 82 | .08 (5 min.) | 7 |
| Non-response questionnaire letter | 81 | 1 | 81 | .08 (5 min.) | 7 |
| Second postcard | 60 | 1 | 60 | .03 (2 min.) | 2 |
| Survey | 35 | 1 | 35 | .33 (20 min.) | 12 |
| Main Study | | | | | |
| Survey invitation letter | 5,042 | 1 | 5,042 | .08 (5 min.) | 403 |
| Reminder postcard | 5,042 | 1 | 5,042 | .03 (2 min.) | 151 |
| Non-response letter | 4,173 | 1 | 4,173 | .08 (5 min.) | 334 |
| Non-response questionnaire letter | 4,073 | 1 | 4,073 | .08 (5 min.) | 326 |
| Second postcard | 3,063 | 1 | 3,063 | .03 (2 min.) | 92 |
| Survey | 1,765 | 1 | 1,765 | .33 (20 min.) | 582 |
| Total | | | | | 1927 |

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 <http://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.

- 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). (<http://www.fda.gov/downloads/Drugs/ScienceResearch/ResearchAreas/DrugMarketingAdvertisingandCommunicationsResearch/ucm152860.pdf>).
- PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines (2008). (http://phrma.org/sites/default/files/pdf/phrma_guidingprinciplesdec08final.pdf).
- Dillman, D.A., J.D. Smyth, and L.M. Christian, *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method, 4th ed.* Hoboken, NJ: John Wiley & Sons, Inc. (2014).

- American Association for Public Opinion Research, "Address-based Sampling" (2016). (http://www.aapor.org/AAPOR_Main/media/MainSiteFiles/AAPOR_Report_1_7_16_CLEAN-COPY-FINAL.pdf).
- Millar, M.M. and D.A. Dillman, "Improving Response to Web and Mixed-Mode Surveys," *Public Opinion Quarterly* 1–21 (2011).
- Shaw, M.J., T.J. Beebe, H.L. Jensen, and S.A. Adlis, "The Use of Monetary Incentives in a Community Survey: Impact on Response Rates, Data Quality, and Cost," *Health Services Research* 35:1339–1346 (2011).
- Montaquila, J.M., J.M. Brick, D. Williams, K. Kim, et al., "A Study of Two-Phase Mail Survey Data Collection Methods," *Journal of Survey Statistics and Methodology* 1(1), 66–87 (2013).

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Medical Devices—Quality Systems Survival: Success Strategies for Production and Process Controls/Corrective and Preventative Action; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA), Office of Regulatory Affairs, Southwest Regional Office, in co-sponsorship with the FDA Medical Device Industry Coalition, Inc. (FMDIC), is announcing a public workshop entitled "Medical Devices—Quality Systems Survival: Success Strategies for Production and Process Controls/Corrective and Preventative Action". The public workshop is intended to seek input from representatives of medical device manufacturers and other stakeholders, on best practices, what has worked for them and what FDA can do to inspire