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 BURDEN [1]

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.

1. 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).*
2. PhRMA Guiding Principles: Direct-to-Consumer Advertisements About Prescription Medicines (2008). (*http://phrma.org/sites/default/files/pdf/phrmaguidingprinciplesdec08final.pdf).*
3. 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).
4. 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).*
5. Millar, M.M. and D.A. Dillman, ''Improving Response to Web and Mixed-Mode Surveys,'' *Public Opinion Quarterly* 1–21 (2011).
6. 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).
7. 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.

[FR Doc. 2016–04220 Filed 2–26–16; 8:45 am]

BILLING CODE 4164–01–P

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

quality efforts. This event will also focus on various topics of interest for those industry representatives who are responsible to insure compliance with FDA regulations.

DATES: The meeting will be held on April 15, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at Courtyard and Towne Place Suites by Marriott, DFW Airport North/Grapevine, 2200 Bass Pro Ct., Grapevine, TX 76051. Directions and lodging information are available at the FMDIC, Inc. Web site at *http://www.fmdic.org/*.

FOR FURTHER INFORMATION CONTACT: Staci McAllister, Consumer Safety Technician, Food and Drug Administration, 4040 N. Central Expressway, Suite 300, Dallas, TX 75204, 214–253–5259, FAX: 214–253–5314, *staci.mcallister@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The workshop is being held in response to the interest in the topics discussed from small medical device manufacturers in the Dallas District area. This workshop helps achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) as an outreach activity by Government agencies to small businesses.

The goal of the public workshop is to present information that will enable manufacturers and regulated industry to better comply with FDA's medical device requirements. Please visit the *http://www.fmdic.org/* Web site for the agenda and for information about the presenters at the workshop.

II. Participation in the Public Workshop

Registration: FMDIC has early registration ($250 for industry/$150 for government with ID/$50 for students) available until March 14, 2016. Registration after March 14, 2016, increases to $300 for industry, $200 for government with ID, with student registration staying the same, at $50. To register online, please visit *http://www.fmdic.org/*. As an alternative, send the registration information including the registrant's name, title, organization, address, telephone and fax numbers, and email address (for each registrant), along with a check or money order (covering all registration fees) payable to the FMDIC, Inc., to FMDIC Registrar, 4447 N. Central Expressway, Suite 110 PMB197, Dallas, TX 75205. FMDIC, Inc. accepts registrations onsite on the day of the event beginning at 7:30 a.m. at the regular registration fee stated above. Registration on site will be accepted on a space available basis on the day of the public workshop beginning at 7:30 a.m. Please note that due to popularity, similar past events have reached maximum capacity well before the day of the event. The cost of registration at the site is $300 payable to the FMDIC, Inc. The registration fee will be used to offset expenses of hosting the event, including continental breakfast, lunch, audiovisual equipment, venue, materials, and other logistics associated with this event.

If you need special accommodations due to a disability, please contact Staci McAllister (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop.

Dated: February 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04221 Filed 2–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0631]

Requirements for Transactions With First Responders Under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy.'' This guidance describes FDA's compliance policy regarding certain requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) for trading partners engaged in transactions with first responders. This compliance policy is in effect until further notice by FDA.

DATES: Effective February 29, 2016. For information about enforcement dates, please see the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may submit comments as follows:

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–D–0631 for ''Requirements for Transactions with First Responders under Section 582 of the Federal Food, Drug, and Cosmetic Act—Compliance Policy; Guidance for Industry.'' 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.