(Pub. L. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the Patient Protection and Affordable Care Act (PPACA)) were signed into law in 2010. The PPACA established competitive private health insurance markets, called Marketplaces or Exchanges, which give millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that are certified as meeting certain standards. The PPACA added section 1150A of the Social Security Act, which requires pharmacy benefit managers (PBMs) to report prescription benefit information to the Department of Health and Human Services (HHS). PBMs are third-party administrators of prescription programs for a variety of types of health plans, including QHPs. The Centers for Medicare and Medicaid Services (CMS) files this information collection request (ICR) in connection with the prescription benefit information that PBMs must provide to HHS under section 1150A. The burden estimate for this ICR reflects the time and effort for PBMs to submit the information regarding PBMs and prescription drugs. *Form Number:* CMS–10725 (OMB control number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits), *Number of Respondents:* 40; *Number of Responses:* 275. *Total Annual Hours:* 1,400. For questions regarding this collection contact Ken Buerger at 410–786–1190.

Dated: January 23, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–01463 Filed 1–27–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5900]

Agency Information Collection Activities; Proposed Collection; Comment Request; Endorser Status and Explicitness of Payment in Direct-to-Consumer 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 a proposed study entitled ''Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion.''

DATES: Submit either electronic or written comments on the collection of information by March 30, 2020.

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 March 30, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 30, 2020. 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–5900 for ''Endorser Status and Explicitness of Payment in Direct-to-Consumer 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: *https://www.govinfo.gov/content/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, 10A–12M, 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. 3501–3521), 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.

Endorser Status and Explicitness of Payment in Direct-to-Consumer Promotion; 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.

The Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotional material 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 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 will inform the first topic area.

Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a direct-to-consumer (DTC) survey conducted in 1999.

Advertisers have used celebrity endorsers for years, and DTC pharmaceutical promotion is no different. As researchers studied the influence of celebrity endorsers, they theorized that a correspondence bias occurs in which people believe that the endorser truly believes what they are saying. LaTour and Smith (Ref. 1) examined whether a pharmacist, physician, celebrity, or consumer would be most persuasive in advertisements for four different types of OTC products. They found that physicians and pharmacists were the most likely to lead to purchase intentions, followed by consumers, and lastly, by celebrities. There were no differences among types of OTC product.

Bhutada and Rollins (Ref. 2) recently completed a study examining the role of endorser type (*i.e.,* celebrity vs. expert vs. non-celebrity), and endorser and consumer gender in product DTC ads. They found, like LaTour and Smith (Ref. 1), that expert endorsers were thought of as higher in credibility and generally resulted in the same amount of attention as celebrities. The authors did not find that these endorsers resulted in greater intentions to pursue the drug product.

We propose to extend previous research by examining four types of endorsers in two separate studies (celebrity, physician, patient, influencer [1]) and examining whether the presence of a disclosure of their payment status influences participant reactions. We propose to also test two different types of disclosure language—one direct and more consumer-friendly, and one less direct.

To complete this research, we propose the following concurrent studies.[2]

Study A

[1] ''Influencer'' is a ''regular'' person who has gained a following on a blog, a Twitter feed, or other social media medium.

[2] For case allocation, the literature suggests that some proportion of consumers may not recall seeing the disclosure statement in the advertisement (see, for example, Boerman et al., Ref. 3). Rather than allotting equal numbers of cases to each condition, we will assign more cases to the disclosure present condition to increase power in these cells.

TABLE 1a—STUDY 1 DESIGN—PRETEST

[0.80 power, 0.10 alpha, small effect size f=.2]

Payment disclosure	Endorser			Total
	Celebrity	Physician	Patient	
Present	50	50	50	150
Absent	33	33	33	99
Total	83	83	83	249

TABLE 1b—STUDY 1 DESIGN—MAIN STUDY

[0.90 power, 0.05 alpha, small effect size f=.2]

Payment disclosure	Endorser			Total
	Celebrity	Physician	Patient	
Present	81	81	81	243
Absent	54	54	54	162
Total	135	135	135	405

Study A will manipulate endorser type (three levels: Celebrity, physician, patient) and payment disclosure (two levels: Present, absent) within a print DTC ad for a fictitious acne product. For this study, we will recruit 654 general population individuals (249 pretest; 405 main study) from a national nonprobability internet panel called Dynata, formerly ResearchNow. All participants must report familiarity with the celebrity to be included in our study. The celebrity will be one who has publicly spoken out about acne. We are not divulging the identity of the celebrity in this public forum to maintain the integrity of our research process. Stock photos will be used to depict a physician and a patient in the other experimental conditions. Participants will be randomly assigned to see one of the endorsers and to see the ad either with or without a payment disclosure. The payment disclosure in Study 1 will be determined in cognitive testing, but will be similar to: ''[Endorser] has been paid to appear in this ad for Drug X.''

Study B

TABLE 2a—STUDY 2 DESIGN—PRETEST

[0.80 power, 0.10 alpha, small effect size f=.2]

Payment Disclosure	Endorser		Total
	Influencer	Patient	
Present-Direct	50	50	100
Present-Indirect	50	50	100
Absent	33	33	66
Total	133	133	266

TABLE 2b—STUDY 2 DESIGN—MAIN STUDY

[0.90 power, 0.05 alpha, small effect size f=.2]

Payment Disclosure	Endorser		Total
	Influencer	Patient	
Present-Direct	81	81	162
Present-Indirect	81	81	162
Absent	54	54	108
Total	216	216	432

In Study B we will also manipulate endorser type, examining a patient and an internet influencer, one who provides online content to a number of followers. We will also manipulate the explicitness of the payment disclosure in addition to its presence, resulting in a two (endorser: Influencer, patient) by three (payment disclosure: Present-direct, present-indirect, absent) between-subjects design. The disclosure will be direct (*e.g.,* ''Paid ad . . .''), indirect (*e.g.,* #sp for ''sponsored''), or absent. The setting for this study will be an Instagram post for a fictitious endometriosis product. This study partially replicates Study A and extends it by further tweaking the explicitness of payment as another manipulated variable and using a different set of

endorser types and in a different promotional setting.

For Study B, we will recruit 698 (266 pretest; 432 main study) followers of an internet influencer who maintains an Instagram page with more than 500,000 followers and has posted about endometriosis. As in the first study, we are not revealing the influencer's identity to maintain the integrity of the study.

In both studies, we are interested in the role of endorsement and payment status on participants' recall, benefit and risk perceptions, and behavioral intentions. Participants will view one promotional piece and answer questions via the internet. The study is expected to take less than 20 minutes to complete. Dependent variables will include attention to disclosure statement and risk/benefit information; retention of risk/benefit information; recognition of piece as promotion and endorser as paid; perceived benefits and risks, attitudes toward the product, endorser, and ad; and behavioral intentions such as asking a doctor about the drug.

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Study 1 Screener	933	1	933	0.08 (5 minutes)	74.64
Study 1 Pretest	249	1	249	0.33 (20 minutes)	82.17
Study 1 Main test	405	1	405	0.33 (20 minutes)	133.65
Study 2 Screener	1,417	1	1,417	0.08 (5 minutes)	113.36
Study 2 Pretest	266	1	266	0.33 (20 minutes)	87.78
Study 2 Main test	432	1	432	0.33 (20 minutes)	142.56
Total					634.16

[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. LaTour, C. and M. Smith, (1986). ''A Study of Expert Endorsement of OTC Pharmaceutical Products.'' *Journal of Pharmaceutical Marketing & Management, 1(2),* pp. 117–128.

2. Bhutada, N.S. and B.L. Rollins (2015). ''Disease-Specific Direct-to-Consumer Advertising of Pharmaceuticals: An Examination of Endorser Type and Gender Effects on Consumers' Attitudes and Behaviors.'' *Research in Social & Administrative Pharmacy, 11(6),* pp. 891–910.

3. Boerman, S.C., L.M. Willemsen, and E.P. Van Der Aa (2017). ''This post is sponsored' Effects of Sponsorship Disclosure on Persuasion Knowledge and Electronic Word of Mouth in the Context of Facebook.'' *Journal of Interactive Marketing, 38,* pp. 82–92.

Dated: January 21, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01408 Filed 1–27–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5606]

Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Arthroscopy Pump Tubing Sets Intended for Multiple Patient Use—Premarket Notification (510(k)) Submissions.'' FDA has developed this draft guidance document to assist in the preparation of premarket notification submissions (510(k)) for arthroscopy pump tubing sets intended for multiple patient use. This draft guidance outlines the device design considerations, risk mitigation strategies, and testing recommendations for arthroscopy pump tubing sets intended for multiple patient use. This draft guidance document also clarifies the terminology used to describe arthroscopy pump tubing sets intended for multiple patient use. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by March 30, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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'').