respondent to include transitional foster care programs (in addition to long-term foster care programs).

- Update instructions on which fields are completed for initial placements and which are completed for transfers within the community-based care program.
- Added citation to related policies in the instructions.
- Reword some fields and instructions for clarity.
- Add field to capture the facility name for children placed in an out-of-network community-based care program.
- Separate fields that capture contact information for the foster family or group home into separate subsections and expand the fields to capture additional contact information (*e.g.,* phone or email) in addition to name and address.

For information about all currently approved forms under this OMB number, see: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202210-0970-008.*

Respondents: ORR grantee and contractor staff; UC; and other Federal agencies.

Annual Burden Estimates

Note: These burden estimates include burden related to the revisions described above and currently approved forms for which we are not proposing any changes.

ESTIMATED BURDEN HOURS FOR RESPONDENTS

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Placement Authorization (Form P–1)	262	536	0.08	11,235
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	262	536	0.08	11,235
Notice of Placement in a Restrictive Setting (Form P–4)	15	114	0.33	564
Community-Based Care Placement Memo (Form P–5)	110	337	0.25	9,268
UC Referral (Form P–7)	25	4,909	1.00	122,725
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	262	19	0.25	1,245
Medical Checklist for Transfers (Form P–9A)	262	49	0.08	1,027
Medical Checklist for Influx Transfers (Form P–9B)	262	96	0.17	4,276
Transfer Request (Form P–10A)	262	67	0.42	7,373
Transfer Request (Form P–10A)	275	67	0.33	6,080
Influx Transfer Request (Form P–10B)	262	96	0.42	10,564
Transfer Summary and Tracking (Form P–11)	262	67	0.17	2,984
Program Entity (Form P–12)	262	12	0.50	1,572
UC Profile (Form P–13)	262	468	0.75	91,962
ORR Transfer Notification—ORR Notification to Immigration and Customs Enforcement Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P–14)	262	67	0.17	2,984
Family Group Entity (Form P–15)	25	120	0.08	240
Influx Transfer Manifest (Form P–16)	3	12	0.33	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	262	56,213	0.50	7,363,903
Notice of Administrative Review (Form P–18)	200	1	0.83	166
Estimated Annual Burden Hours Total				7,649,415

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores* v. *Reno Settlement Agreement,* No. CV85–4544–RJK (C.D. Cal. 1996); 45 CFR part 411; *Lucas R. et al.* v. *Azar et al.* (Case No. CV 18–5741–DMG (PLAx)) Preliminary Injunction.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–09048 Filed 4–27–23; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1886]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Endorser Status and Actual Use in Direct-to-Consumer Television Ads

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: Submit written comments (including recommendations) on the collection of information by May 30, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Endorser Status and Actual Use in Direct-to-Consumer Television Ads.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: PRA Staff, 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.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

Endorser Status and Actual Use in Direct-to-Consumer Television Ads

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 (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 mission of the Office of Prescription Drug Promotion (OPDP) is to protect the public health by helping to ensure that prescription drug promotional material is truthful, balanced, and accurately communicated. 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 the characteristics of the disease and product 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, advertising features.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are 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 home page at *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

The objective of the present research is to conduct experimental studies to examine issues related to endorsers in direct-to-consumer (DTC) prescription drug promotion. This study complements one that has recently been completed (FDA–2019–N–5900, OMB control number 0910–0894, Expiration Date: March 31, 2023). As that study examined a number of different endorser types in print or internet settings and focused on examining how various disclosures of the payment status of the endorser influenced audience reactions, this proposed research extends the prior research by examining actual-use disclosures and a different medium, television ads. Prior research has shown that endorsements by expert physicians and pharmacists were the most likely to lead to purchase intentions, followed by endorsements by consumers, and lastly, by celebrities (Refs. 1 and 2).

For healthcare providers (HCPs) endorsing a prescription drug product, guiding industry principles advise that advertisements should contain a disclosure that the HCP has been compensated for the endorsement (Ref. 3). Industry guiding principles further recommend that an advertisement disclose when an actor is being used as an HCP to promote DTC prescription drugs.

Pharmaceutical firms also often use everyday people, either actual patients or actors portraying patients, in DTC promotion, relying on qualities of identification with the individual endorsing the product and perceived credibility (Ref. 4). While industry guidelines recommend that companies choosing to feature actors in the roles of HCPs in a DTC television or print ad acknowledge in the ad that actors are being used, the guidelines do not mention disclosures that the ''patient'' in an ad is being portrayed by an actor (Ref. 3). Some advertisers endeavor to gain credibility among viewers by using actual patients to endorse the product, with a disclosure that states they are actual users of the product (''actual-use disclosure'') (Ref. 5).

The present research will specifically examine the influence of two independent variables—endorser type (patient, physician) and an actual-use disclosure (utilizer, actor, none)—in television advertisements. Dependent variables will include perceptions of the risks and benefits of the promoted prescription drug, attitudes toward and perceptions of the endorser, attention paid to the ad, and behavioral intentions. Because age and education level may affect perceptions of the ad, we plan to explore whether age and education level influence these effects.

This research will involve two studies. Studies 1 and 2 will use a 2×3 factorial design run concurrently and independently with a sample of consumers who have been diagnosed with diabetes (Study 1) or rheumatoid arthritis (Study 2), each watching a DTC television ad for a fictitious drug indicated to treat the corresponding medical conditions. The ad will be manipulated to assess the impact of two categories of commonly used industry spokespeople: a patient and a physician. We will test three actual-use disclosure conditions: (1) an actual-use disclosure that indicates that the endorser either uses or prescribes the prescription drug in real life (*i.e.,* utilizer), (2) an actual-use disclosure that specifies the endorser is an actor, and (3) a control with no actual-use disclosure. The design for Studies 1 and 2 is presented in table 1.

TABLE 1—STUDY 1 AND STUDY 2 EXPERIMENTAL DESIGN

Actual-use disclosure	Endorser type	
	Patient	Physician
Utilizer.		
Actor.		
None.		

In both studies, participants will be randomly assigned to one of six experimental conditions (see table 1), view their assigned stimulus, complete a survey, and provide feedback on one of the other ad versions. We will conduct pretests with 126 consumers who self-identify as having been diagnosed with diabetes and 126 consumers who self-identify as having been diagnosed with rheumatoid arthritis, recruited from a web-based research vendor. For the main study, we will then recruit 648 consumers who self-identify as having been diagnosed with diabetes and 648 consumers who self-identify as having been diagnosed with rheumatoid arthritis. Each participant will see one of six versions of a television ad for a fictitious prescription diabetes or rheumatoid arthritis treatment, as reflected in table 1. They will answer a questionnaire designed to take no more than 20 minutes.

In the **Federal Register** of September 23, 2022 (87 FR 58099), FDA published

a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Study 1 Pretest					
Study 1 Pretest Screener Completes	630	1	630	.03 (2 minutes)	18.9
Study 1 Pretest Questionnaire Completes	126	1	126	.30 (18 minutes)	38
Study 2 Pretest					
Study 2 Pretest Screener Completes	420	1	420	.03 (2 minutes)	12.6
Study 2 Pretest Questionnaire Completes	126	1	126	.30 (18 minutes)	38
Study 1 Main Study					
Study 1 Main Study Screener Completes	3,240	1	3,240	.03 (2 minutes)	97.2
Study 1 Main Study Questionnaire Completes	648	1	648	.30 (18 minutes)	194
Study 2 Main Study					
Study 2 Main Study Screener Completes	2,160	1	2,160	.03 (2 minutes)	64.8
Study 2 Main Study Questionnaire Completes	648	1	648	.30 (18 minutes)	194
Total					657.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format ''[number of minutes per response]/60.''

References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. 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, ''A Study of Expert Endorsement of OTC Pharmaceutical Products,'' *Journal of Pharmaceutical Marketing & Management,* Vol. 1, Issue 2, pp. 117–128, 1986.
2. Bhutada, N.S. and B.L. Rollins, ''Disease-Specific Direct-to-Consumer Advertising of Pharmaceuticals: An Examination of Endorser Type and Gender Effects on Consumers' Attitudes and Behaviors,'' *Research in Social and Administrative Pharmacy,* Vol. 11, Issue 6, pp. 891–900, 2015.
3. *Pharmaceutical Research and Manufacturers of America (PhRMA), ''PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines,'' *Pharmaceutical Research and Manufacturers of America,* Washington, DC, *https://www.phrma.org,* revised October 2018, available at *https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Guiding_Principles_2018.pdf* (accessed May 18, 2022).
4. *Schouten, A.P., L. Janssen, and M. Verspaget, ''Celebrity vs. Influencer Endorsements in Advertising: The Role of Identification, Credibility, and Product-Endorser Fit,'' *International Journal of Advertising,* Vol. 39, Issue 2, pp. 258–281, 2020, *https://doi.org/10.1080/02650487.2019.1634898.*
5. *Bulik, B.S., ''Merck Adds Real Patient to 'TRU' Keytruda TV Ad,'' Fierce Pharma, September 27, 2017, available at *https://www.fiercepharma.com/marketing/new-merck-tv-ad-for-keytruda-continues-tru-theme-but-now-features-real-patient* (accessed May 18, 2022).

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08965 Filed 4–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–3208]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: Submit written comments (including recommendations) on the collection of information by May 30, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB