Center for Adoption Support and Education (C.A.S.E) for the continued expansion and use of the National Adoption Competency Mental Health Training Initiative across the nation.

SUMMARY: The ACF, ACYF, Children's Bureau, Division of Capacity Building announces the intent to award a single-source cooperative agreement in the amount of up to $10,000,000 to the Center for Adoption Support and Education in Burtonsville, MD. The purpose of this award is to continue to scale the web-based National Training Initiative for Adoption Competent Mental Health Training program to remaining states in the nation, refine and update the curriculum as needed and perform an updated evaluation regarding current use of the curriculum.

DATES: The proposed period of performance is September 30, 2022 to September 29, 2027.

FOR FURTHER INFORMATION CONTACT: June Dorn, National Adoption Specialist, Division of Capacity Building, 333 C St. SW, Suite 3521B, Washington, DC 20201. Telephone: (202) 205–9450; Email: *June.Dorn@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: Award funds will support the continued expansion and use of the National Training Initiative on Mental Health Competency across the nation. This curriculum was developed through an initial 5-year grant to C.A.S.E. and pilot tested prior to being supplemented and extended for 3 additional years for the further dissemination and integration of this important web-based training in the state child welfare training systems so there would be consistent use of the knowledge imparted by it across all child welfare systems.

This funding will allow for the continued scale up of the web-based trainings for the child welfare workforce and mental health practitioners to remaining states in the nation; the refinement and update of the curricula as needed; and additional and updated evaluation of the curricula.

Statutory Authority: Title II, section 203 of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5113(b)), as amended by CAPTA Reauthorization Act of 2010.

Elizabeth A. Leo,

Senior Grants Policy Specialist, Office of Grants Policy, Office of Administration.

[FR Doc. 2022–20587 Filed 9–22–22; 8:45 am]

BILLING CODE 4184–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1886]

Agency Information Collection Activities; Proposed Collection; 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 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 Actual Use in Direct-to-Consumer Television Ads.''

DATES: Submit either electronic or written comments on the collection of information by November 22, 2022.

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 November 22, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2022. 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–2022–N–1886 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Endorser Status and Actual Use in Direct-to-Consumer Television Ads.'' 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, 240–402–7500.

- 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: *Regarding the collection of information:* JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

For copies of the questionnaire: Amie O'Donoghue, 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 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 (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.

The mission of the 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 DTC prescription drug promotion. This study complements one that is currently in progress (FDA–2019–N–5900, OMB control number 0910–0894, Expiration Date: February 29, 2024). 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 direct-to-consumer (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.

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. *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: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20617 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1847]

Exemption and Exclusion From Certain Requirements of the Drug Supply Chain Security Act for the Distribution of Food and Drug Administration-Approved Naloxone Products During the Opioid Public Health Emergency; Guidance for Industry; 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 a final guidance for industry entitled ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' Combating the opioid overdose epidemic is an urgent public health priority for FDA. Naloxone hydrochloride (''naloxone'') is a medication that rapidly reverses the effects of opioid overdose and is the standard treatment for opioid overdose. FDA understands that naloxone is being made available to underserved communities through entities such as harm reduction programs and is aware of concerns that harm reduction programs are having difficulty acquiring naloxone. FDA is issuing this guidance to clarify the scope of the public health emergency exclusion and exemption under the Drug Supply Chain Security Act as they apply to the distribution of FDA-approved naloxone products indicated for the emergency treatment of opioid overdose to harm reduction programs during the opioid public health emergency. The guidance document is immediately in effect, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 23, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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'').

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–2022–D–1847 for ''Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act for the Distribution of FDA-Approved Naloxone Products During the Opioid Public Health Emergency.'' Received comments 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, 240–402–7500.

- 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