OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–576A Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations

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. The term ''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 requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Organ Procurement Organization's (OPOs) Health Insurance Benefits Agreement and Supporting Regulations; *Use:* The Medicare and Medicaid Programs final conditions for coverage for Organ Procurement Organizations (OPOs) require OPOs to sign agreements with the Center for Medicare and Medicaid Services (CMS) in order to be reimbursed and perform their services. The information provided on this form serves as a basis for continuing the agreements with CMS and the OPOs for participation in the Medicare and Medicaid programs for reimbursement of service. *Form Number:* CMS–576A (OMB Control Number: 0938–0512); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 29. (For policy questions regarding this collection contact Melissa Rice at 410–786–3270.)

Dated: July 16, 2019.

William N. Parham, III,

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

[FR Doc. 2019–15426 Filed 7–18–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3163]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Physician Interpretation of Information About Prescription Drugs in Scientific Publications Versus Promotional Pieces

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, 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: Fax written comments on the collection of information by August 19, 2019.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces.'' Also include the FDA docket number found in brackets in the heading of this document.

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.*

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.

Physician Interpretation of Information About Prescription Drugs in Scientific Publications vs. Promotional Pieces

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 FD&C Act prohibits the dissemination of false or misleading information about medications in consumer-directed and professional prescription drug promotion. As part of its Federal mandate, FDA regulates whether advertising of prescription drug products is truthful, balanced, and accurately communicated (see 21 U.S.C. 352(n)). FDA's regulatory policies are aligned with the principles of free speech and due process in the U.S. Constitution. To inform current and future policies, and to seek to enhance

audience comprehension, FDA's Office of Prescription Drug Promotion (OPDP) conducts research focusing on: (1) Advertising features including content and format, (2) target populations, and (3) research quality. This proposed research focuses on healthcare professionals (HCPs). The proposed collection of information will investigate how physician perception of prescription drug information is influenced by variations in information context (presence of graphical elements and information delivery vehicle—medical journal abstract or sales aid), methodologic rigor of the underlying clinical study (high or low), and time pressure (present versus absent).

A. Ways in Which Information Context and Study Quality May Influence Perceptions

Physicians gain knowledge about medical product uses from a variety of information vehicles including peer-reviewed journal articles, compendia, continuing medical education, and physician-directed promotion by or on behalf of manufacturers. Peer-reviewed scientific publications may report the results of a variety of studies, employing a wide range of methodologies with varying levels of rigor. As a result, information of varying quality is disseminated to the field. Physician detailing sometimes includes information derived from peer-reviewed research that, in this context, serves a dual purpose: To both inform and market a particular product (Ref. 1).

Prior research has examined some impacts of study quality and funding source on physician perception. For example, research by Kesselheim et al. (Ref. 2) on study abstracts examined how methodologic rigor (high, medium, low) and information about the source of funding (industry, National Institutes of Health, none) affected physician perceptions of study quality, prescribing intentions, and interest in reading the full article. Results indicated physician participants were able to distinguish between levels of methodologic rigor. Physicians also used information about the funding source to distinguish materials. They reported less willingness to prescribe the drugs or read the full study from trials funded by industry, regardless of study rigor. Thus, funding source was a contextual factor that impacted physicians' perceptions of the information.

Research has also shown that physician prescribing behavior can be influenced by the context in which the information is delivered. Spurling et al. (Ref. 3) examined the way in which information from a pharmaceutical company was delivered (using conventional promotional techniques such as sales rep visits, journal advertisements, or attendance at pharmaceutical-sponsored meetings versus not using conventional promotional techniques such as participation in company sponsored trials and representatives' visits for nonpromotional purposes) and prescribing outcome across 58 studies. They found conventional promotional techniques were associated with an increase in prescribing and a decrease in prescribing quality. We are proposing to test a different type of contextual factor in this study: Whether the drug information appears in a medical journal abstract or a sales aid.

B. Ways in Which Graphics May Influence Perceptions

Promotional materials about prescription drugs that are directed toward physicians often include a variety of visual elements beyond simple text. In a study of professionally directed prescription drug brochures left for physicians by pharmaceutical representatives, researchers found 95 percent contained a visual graphic (including bar charts, line graphs, pie charts, arrows) accompanying the presentation of data (Ref. 4). An analysis of professionally directed prescription drug print advertisements in medical journals found 80 percent of the ads contained some type of image, and 21 percent contained data-related graphics. A group of two physicians and one pharmacist judged these ads. This group found that of those ads that contained images, 58 percent contained images that minimized the risks of the product and 24 percent of the images in the ads misled about product efficacy (Ref. 5).

C. Ways in Which Time Pressure May Influence Perceptions

We are also interested in how time pressure may impact physician perceptions. Time pressure can impact processing of information (*e.g.,* accuracy and speed) as well as decision making. Physicians are often under pressure to split their work time between myriad duties that may include clinical care, research, mentoring, teaching, and administrative duties (Ref. 6). Individuals under time pressure tend to rely on previously formed attitudes for decision making and have less cognitive capacity to process information (Refs. 7 and 8). This results in different decisions depending on the amount of time available (Ref. 9). Research suggests that in situations with high time pressure or increased ambiguity, experts use intuitive decision-making strategies rather than structured approaches (Refs. 10 and 11). Physicians may therefore tend to rely on intuitive processes rather than evidence-based information under time pressure.

Research has also found that under time pressure, physician adherence to clinical practice guidelines concerning history taking and advice giving can be compromised (Ref. 12). One study that assessed the reading habits of physicians found that with limited time available for critical reading, practitioners relied heavily on abstracts and prescreening of articles by editors (Ref. 13). Thus, time pressure is an element of physicians' practice environment that can impact information gathering and, consequently, decision making, and the quality of health care delivered.

II. Proposed Study

We propose to investigate how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. We propose to test three different contextual presentations of drug information (medical journal abstract, sales aid without graphic design elements, and sales aid with graphic design elements), and two types of study methodological rigor used by Kesselheim et al. (classified as high or low; Ref. 2). We have chosen to test a mock sales aid presentation and a medical journal abstract to examine the potential differences in perception that may arise by presenting the same information in different vehicles. Mirroring the time constraints of practicing physicians, we will examine the role of time pressure by randomly assigning half of the study participants to a limited amount of available time to read the materials. Table 1 describes the study design.

TABLE 1—STUDY DESIGN

			Information context		
			Medical journal abstract	Sales aid without graphic design elements	Sales aid with graphic design elements [2]
Limited Time to Read	Methodological Rigor [1]	High.			
		Low.			
Unlimited Time to Read.		High.			
		Low.			

[1] As defined by Kesselheim et al. (Ref. 2).
[2] For example, colors and background images.

For this proposed study, voluntary participants will be board-certified internists. To examine differences between experimental conditions, we will conduct inferential statistical tests such as analysis of variance (ANOVA). With the sample size described, we will have sufficient power to detect small-to-medium sized effects in the main study.

We plan to conduct one pretest with 158 voluntary participants and one main study with 566 voluntary participants. The purpose of the pretest is to ensure the manipulations are working as intended, and to examine the effectiveness of question wording. In the pretest, participants will answer questions about the study design and questionnaire. The studies will be conducted online. The pretest and main studies will have the same design and will follow the same procedure. Participants will be randomly assigned to one of 12 test conditions (see table 1). Following exposure to the stimuli, they will be asked to complete a questionnaire that assesses comprehension, perceptions, prescribing intentions, and demographics. We anticipate analyzing the data as a full factorial design (main effects and interactions) with two primary comparisons for the information context independent variable: Journal abstract versus sales aid without graphics and sales aid without graphics versus sales aid with graphics. We will also do an exploratory comparison of journal abstract versus sales aid with graphics.

This study will be conducted as part of the research program of the OPDP. OPDP's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated, so that patients and health care providers can make informed decisions about treatment options. OPDP's research program supports this mission by providing 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 we believe are most central to our mission, focusing 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 falls under the topic of both target populations and advertising features.

In the **Federal Register** of October 17, 2018 (83 FR 52490), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received three comments that were PRA related. Within those submissions, FDA received multiple comments that the Agency has addressed.

(Comment) Two comments asked for clarity about the research objectives and hypotheses. One comment asked how FDA will use such knowledge to inform the regulation of prescription drug promotion in the future, particularly the variable of time.

(Response) As described in the 60-day **Federal Register** notice, we propose to investigate how physician perception of professional prescription drug communications is influenced by variations in information context, methodologic rigor of the underlying clinical study, and time pressure. We propose to test three different contextual presentations of drug information (medical journal abstract, sales aid without graphic design elements, sales aid with graphic design elements), and two types of study methodological rigor used by Kesselheim et al. (classified as high or low; Ref. 2). We have chosen to test a mock sales aid presentation and a medical journal abstract to examine the potential differences in perception that may arise by presenting the same information in different vehicles. Mirroring the time constraints of practicing physicians, we will examine the role of time pressure by randomly assigning half of the study participants to a limited amount of available time to read the materials. Our research questions (RQs) are:

RQ 1: Does the information context in which the information appears affect processing of the information?

RQ 2: Does methodological rigor of the study affect processing of the information?

RQ2a: Do physicians correctly interpret the methodological rigor of the study?

RQ3: Does the time available to read the information affect processing of the information?

RQ4: What are the potential interactions between these factors?

Thus, the goal of our study is to understand the ways in which the presentation of information, methodological rigor, and time affect how physicians interpret information about drugs when it comes from different sources. Although we cannot speculate on any future action because of our research studies, the Agency is committed to examining and conducting research that will ensure that any changes are grounded in science and will have the greatest benefit to public health. For this reason, FDA consistently conducts research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing on three main topic areas: Advertising features, including content and format; target populations; and research quality. Results from studies we conduct are evaluated within the broader context of research and findings from other

sources. The broader body of knowledge is used to inform both policy and regulatory approaches.

(Comment) Six comments focused on various aspects of the study design. Comments asked for: (1) Clarity about the reasoning behind inclusion of the aspects of time pressure; (2) how time pressure reflects the reality of the HCP experience; (3) how time pressure will be operationalized; (4) justification for comparison of a sales aid to an abstract; (5) a suggestion to remove one of the sales aid conditions to simplify the design; and (6) more detail about how methodologic rigor will be defined and represented in a sales aid or an abstract. One comment (7) asserted graphics in promotional materials are tested by pharmaceutical companies through market research to ensure correct interpretation and so the presence or absence of graphics cannot predict how HCPs will interpret information in promotional materials. This comment also asserted the 1992 supporting reference in the 60-day **Federal Register** notice was outdated.

(Response to 1–3) Prior research has found that many physicians have limited time to spend reading drug information (Refs. 6–11). To imitate physicians' real-world experiences in this study, half of the participants will be randomly assigned to a condition in which time pressure is present; the other half will experience no time pressure. Those in the time pressure present condition will receive instructions explaining they will have two minutes to review the study description, which will be reevaluated after pretesting. Those without time pressure will be told they have as much time as they need to review the study description.

(Response to 4–5) As described in the 60-day **Federal Register** notice, we have two primary comparisons for the information context independent variable: Journal abstract versus sales aid without graphics, and sales aid without graphics versus sales aid with graphics. We will also do an exploratory comparison of journal abstract versus sales aid with graphics. As further described in the 60-day **Federal Register** notice, we are examining the potential differences in perception that may arise by presenting the same information in different vehicles. The same information will be presented in the context of an abstract and the context of a sales aid. Described another way, we are controlling the text of the information and varying its ''wrapper'' to explore whether the context in which the information appears influences how the information is perceived. A comparison of abstract to sales aid without graphics, and sales aid without graphics to sales aid with graphics will enable us to examine perceptual differences that may arise from the context in which the information occurs. To control for extraneous effects, we are not presenting any other information in the sales aid.

(Response to 6) In addition to studying the presentation of information in different information vehicles (sales aid versus abstract), we will also examine two different levels of methodological rigor, either high or low quality (Ref. 2). Some key differences between the levels of rigor are: Blinding, representative population, and drug safety reported (Ref. 2). For example, the high rigor study that half of the participants will view was a randomized double-blind study that had a representative patient population, and the drug was reported to be safe (Ref. 2). The low rigor study that the other half of the participants will view was open-label (no blinding), was not representative of the patient population, and there was no report of the safety of the drug (Ref. 2). We used the same criteria to develop our stimuli as did Kesselheim et al. (Ref. 2). For example, variables in the high rigor condition included double-blind, active comparator, and representative patient population. Variables in the low rigor condition included open-label, usual care comparator, and a non-representative patient population.

(Response to 7) It is possible that the presence of graphics affects the impressions of the product, which we are assessing in this study. To address the comment about the date of the referenced research, we conducted an additional search of the literature. In a study by Othman et al. (Ref. 14), 28 percent of claims made in pharmaceutical advertisements were judged clear and not misleading. This suggests that 72 percent were misleading or unclear. We welcome the opportunity to review unpublished market research or other available data to inform this study.

(Comment) One comment questioned the sufficiency of the proposed analysis plan based on the information provided in the notice and asked for clarity about the main dependent variables.

(Response) Our primary dependent variables are: Likelihood to prescribe, confidence in study results, interpret data cautiously, would use data in prescribing, credibility of data, bias of data, and trust in promotion. We will conduct ANOVAs (for continuous variables) and logistic regressions (for dichotomous variables) with interaction terms and planned comparisons to test the research questions. We have outlined our research questions above.

(Comment) Three comments requested FDA disseminate the study stimuli, and one comment requested disseminating the questionnaire prior to requesting comments.

(Response) We have described the purpose of the study, the design, the population of interest, and the estimated burden. The 60-day notice published on October 17, 2018, provided an email address to obtain copies of the questionnaire (83 FR 52490 at 52491, column 3) and we provided the questionnaire to individuals upon request. The content of the stimuli is taken from Kesselheim et al. (Ref. 2). Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research.

(Comment) Two comments questioned limiting the sample to board-certified internists and not including specialists, particularly those who specialize in diabetes treatment and endocrinologists. Relatedly, one comment suggested a sample size of at least 200 physicians.

(Response) Our study is a partial replication of the Kesselheim et al. (Ref. 2) study. In that study, internists were used as the target population and in keeping with the replication, we chose to evaluate internists as well. We encourage future research to expand to other physician specialties. The sample will provide us enough power to detect a medium-sized effect between the study variables.

(Comment) Two comments suggested changing the scale range of the questions so that all of the questions use a consistent scale range.

(Response) We are using several questions that have been validated in previous studies. Therefore, some of the scales have various lengths. We chose to maintain scale range to maintain validation rather than editing scales for consistency.

(Comment) Seven comments suggested changes to the questionnaire. These suggested changes included: (1) Adjusting the wording of the question that asks about the importance of the target study ''to ensure more consistent interpretation by respondents, such as importance of study findings on respondent decision making, etc.''; (2) revising the question about perceptions of bias to avoid the respondent making the assumption that the data presentation is biased; (3) deletion of questions about perceptions of risk; (4) deletion of the question about places

where information about unapproved drugs has been encountered because it appears unrelated to the study goals; (5) addition of a response choice to the question measuring decision to include colleagues as a source of information; (6) addition of screening questions about statistical training; and (7) addition of a question about how much time is typically spent reviewing materials such as this.

(Responses) (1) The study importance question is taken from Kesselheim et al. (Ref. 2) and we did not encounter any issues with this question during cognitive interviews. (2) Perceptions of the amount of potential bias is one of our primary dependent measures. We will change the wording of this question to read ''How unbiased or biased is the study you saw?'' [1 = very unbiased; 5 = very biased]. (3) We acknowledge participants may have a difficult time answering questions about risk. We believe an overall risk-benefit assessment is possible based on the information provided. Thus, we have decided to retain these questions as variables of secondary interest. (4) The question about where participants may encounter information about unapproved drugs is taken from the Healthcare Professional Survey of Professional Prescription Drug Promotion (Docket No. FDA–2018–N–0215). We have included it here so that we may compare results across the two populations in an exploratory manner. (5) We will add a question about seeking information in response to the data participants see in the study that includes a response choice that captures desire to discuss drug information with a colleague prior to prescribing. (6) We will add a question about statistical training to the demographic section of the questionnaire. (7) We will add a question about how long participants typically spend reading materials of this type.

(Comment) One comment suggested moving the non-terminating demographic screener questions to the end of the survey.

(Response) We appreciate this suggestion. We have moved these questions to the end of the survey.

(Comment) One comment asked that the results be broadly and systematically disseminated.

(Response) The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations at trade and academic conferences, submissions in publications, publishing articles, and internet postings.

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	Total hours
Pretest screener	197	1	197	0.03 (2 minutes)	6
Main Study screener	700	1	700	0.03 (2 minutes)	21
Completes, Pretest	158	1	158	0.33 (20 minutes)	53
Completes, Main Study	566	1	566	0.33 (20 minutes)	187
Total	1,621		1,621		267

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. 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.

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13. Saint, S., D.A. Christakis, S. Saha, et. al, ''Journal Reading Habits of Internists,'' *Journal of General Internal Medicine,* 15:881–884, 2000.
14. *Othman, N., A. Vitry, and E.E.

Roughead, ''Quality of Pharmaceutical Advertisements in Medical Journals: A Systematic Review,'' *PLoS Medicine,* 4:e6350, *https://doi.org/10.1371/journal.pone.0006350*, 2009.

Dated: July 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15350 Filed 7–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–2870]

Electronic Submission; Data Standards; Support for Geopolitical Entities, Names, and Codes

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the adoption of the current version of the Geopolitical Entities, Names, and Codes (GENC) Standard on December 17, 2020. The GENC Standard is the U.S. Government profile of International Organization for Standardization (ISO) 3166 ''Codes for the Representation of Names of Countries and Their Subdivisions.'' It specifies an authoritative set of country codes and names for use by the U.S. Government for information exchange, using ISO 3166 names and code elements wherever possible, with modifications only when necessary to comply with U.S. law and U.S. Government recognition policy. Adopting the GENC Standard will enable FDA to be in conformance with U.S. Government naming and recognition policies. You may submit comments at any time regarding the appropriateness or timing of FDA's adoption of the GENC Standard.

ADDRESSES: You may submit either electronic or written comments 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–2019–N–2870 for ''Electronic Submission; Data Standards; Support for Geopolitical Entities, Names, and Codes.'' 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.

- 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.gpo.gov/fdsys/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.

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SUPPLEMENTARY INFORMATION: On December 17, 2015, FDA began supporting GENC as the FDA standard for representing countries and their principal subdivisions. ISO is an organization that creates standards documents to provide requirements, specifications, and guidelines that can be followed by regulatory agencies and industry (*https://nsgreg.nga.mil/genc/discovery*). Before adopting GENC as its standard, FDA represented countries using ISO 3166–1 alpha-3 and represented countries' principal subdivisions using ISO 3166–2. Before adopting ISO 3166 as its standard, FDA represented countries using Federal Information Processing Standards (FIPS) 10–4 and represented principal subdivisions of the United States using FIPS 5–2 (*https://nsgreg.nga.mil/doc/view?i=2564*). FIPS are publicly announced standards developed by the U.S. Government for use in computer systems by nonmilitary Government Agencies and industry.

Public Law 80–242 (1947) requires the U.S. Government to use geographic names that have been approved by the U.S. Board on Geographic Names (BGN). ISO 3166 contains a small set of country