Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket Nos. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD.

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23725 Filed 10–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1026]

Agency Information Collection Activities; Proposed Collection; Comment Request; Text Analysis of Proprietary Drug Name Interpretations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 ''Text Analysis of Proprietary Drug Name Interpretations.''

DATES: Submit either electronic or written comments on the collection of information by January 3, 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 January 3, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 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–2021–N–1026 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Text Analysis of Proprietary Drug Name Interpretations.'' 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: 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, *Ila.Mizrachi@fda.hhs.gov.*

For copies of the questionnaire: 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.

Text Analysis of Proprietary Drug Name Interpretations

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 Office of Prescription Drug Promotion's (OPDP) mission is to protect the public health by helping to ensure that prescription drug promotion 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. Our research focuses in particular on three main topic areas: (1) Advertising features, including content and format; (2) target populations; and (3) 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 all three topic areas.

Because we recognize 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, which can be found 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.

As part of the prescription drug regulatory review process, sponsors propose proprietary names for their products. These names undergo a proprietary name review that involves the Office of Drug Safety, the relevant medical office, and OPDP. OPDP reviews names to assess for alignment with the FD&C Act, which provides, among other things, that labeling can misbrand a product if false or misleading representations are made (see 21 U.S.C. 321(n) and 352(a)). A proprietary name that appears in labeling could result in such misbranding if it is false or misleading. OPDP reviews, among other things, whether names: (1) Overstate the efficacy or safety of the drug; (2) suggest drug indications that are not accurate; (3) suggest superiority without substantiation; or (4) are of a fanciful nature that misleadingly implies unique effectiveness or composition. It would be helpful in OPDP's review of promotional implications of proprietary names for data on consumer and prescriber interpretations of proposed proprietary names to be more readily available for consideration. The proposed research will utilize text analysis (*e.g.,* topic modeling and sentiment analysis) to ascertain how consumer and primary care physician (PCP) populations interpret prescription drug names, which will assist OPDP's consideration of promotional implications.

This proposed research builds upon and extends OPDP research entitled ''Empirical Study of Promotional Implications of Proprietary Prescription Drug Names'' (86 FR 14440). That research involves an experimental design intended to assess names that potentially overstate the efficacy of a product. In contrast, the proposed research involves a survey design that comprises primarily open-ended questions intended to generate text for analysis, an approach that is unrestricted in its ability to assess different types of promotional implications (*e.g.,* minimization of risk and unsubstantiated superiority, in addition to overstatement of efficacy). The proposed research will add to the depth and breadth of knowledge we can draw from during the review of proposed proprietary drug names.

The key objectives of the proposed research are as follows:

1. To apply new techniques such as topic modeling and sentiment analysis (forms of text analysis) to answer OPDP's research questions about consumer and PCP interpretations of proprietary prescription drug names.
2. To help develop a methodological approach for assessing consumer and prescriber interpretations of drug names, which can potentially be used in the future as a standard assessment tool.

Our methodological approach will involve nationally representative samples. Consumers will be recruited from Ipsos Public Affairs KNOWLEDGEPANEL. PCPs will be recruited using a two-stage approach that will begin with a purchased list of PCPs based on the American Medical Association Physician Masterfile. These members will then be matched to one or more sample provider lists to recruit PCP participants for this study. We propose a sample of 300 consumers and 300 PCPs for the main study. We have designed a within-subjects experiment in which participants will be exposed to multiple drug names to maximize power to find differences with this sample size. The stimuli will comprise 60 experimental names and 60 control names. Participants will be randomized to 1 of 10 groups so that no one responds to more than 12 names in total. Each participant will see six experimental names and six control names. The experimental names will be names with suspected promotional implications, whereas the control names will not have suspected promotional implications. Names will be viewed in random order. Participants will respond in open-ended text boxes about their perceptions of each drug name. Supplementary closed-ended questions may also be presented. We will conduct text analysis of the responses and present descriptive results for individual drug names by participant cohort (*i.e.,* consumers vs. PCPs), and

we will also code and compare responses across types of drug names.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
General Consumer Population					
Pretest 1 screener (assumes 80% eligible)	22	1	22	0.08 (5 minutes)	1.8
Pretest 1 survey	15 + 10% [2] = 17	1	15 + 10% [2] = 17	0.33 (20 minutes)	5.6
Pretest 2 screener (assumes 80% eligible)	22	1	22	0.08 (5 minutes)	1.8
Pretest 2 survey	15 + 10% [2] = 17	1	15 + 10% [2] = 17	0.33 (20 minutes)	5.6
Main study screener completes (assumes 80% eligible).	413	1	413	0.08 (5 minutes)	33
Main study survey completes	300 + 10% [2] = 330	1	300 + 10% [2] = 330	0.33 (20 minutes)	108.9
PCP Population					
Pretest 1 screener (assumes 30% eligible)	57	1	57	0.08 (5 minutes)	4.6
Pretest 1 survey	15 + 10% [2] = 17	1	15 + 10% [2] = 17	0.33 (20 minutes)	5.6
Pretest 2 screener (assumes 30% eligible)	57	1	57	0.08 (5 minutes)	4.6
Pretest 2 survey	15 + 10% [2] = 17	1	15 + 10% [2] = 17	0.33 (20 minutes)	5.6
Main study screener completes (assumes 30% eligible).	1,100	1	1,100	0.08 (5 minutes)	88
Main study survey completes	300 + 10% [2] = 330	1	300 + 10% [2] = 330	0.33 (20 minutes)	108.9
Total					374

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] As with most online and mail surveys, it is always possible that some participants are in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the study.

Dated: October 22, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23731 Filed 10–29–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–1318, FDA–2020–E–1319, FDA–2020–E–1320, FDA–2020–E–1321, FDA–2020–E–1322, and FDA–2020–E–1323]

Determination of Regulatory Review Period for Purposes of Patent Extension; VYONDYS 53

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for VYONDYS 53 and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by January 3, 2022. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by May 2, 2022. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 January 3, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 3, 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.

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- 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'').

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