Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–05332 Filed 3–15–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5666]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by April 15, 2021.

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 ''Empirical Study of Promotional Implications of Proprietary Prescription Drug Names.'' 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.

Empirical Study of Promotional Implications of Proprietary Prescription Drug Names

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 our research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first two topic areas, advertising features and target populations.

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

During the prescription drug approval 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, among other things, provides that labeling can misbrand a product if false or misleading representations are made (see 21 U.S.C. 321(n), 352(a)). A proprietary name, which appears in labeling, could result in such misbranding if it is false or misleading. OPDP focuses its review on identifying names that overstate the efficacy or safety of the drug, suggest drug indications that are not accurate, suggest superiority without substantiation, or are of a fanciful nature that misleadingly implies unique effectiveness or composition. This research will focus on the effect on consumers' and/or healthcare providers' perceptions of a drug product of names that overstate the efficacy of the drug product. An overstatement of efficacy can occur, for example, in terms of level of efficacy, in which the degree of relief is overstated, or in terms of the type of effect, in which case there is a mismatch with the indication of the drug. The drug products that are studied will be fictitious, and whether the names overstate the drug products' efficacy will be determined with regard to the products' fictitious degree of efficacy.

The proposed study is designed to provide systematic, empirical evidence to answer two research questions:

- *Primary research question:* How, if at all, do names that suggest the medical condition for which a drug is indicated affect consumers' and/or healthcare providers' perceptions of prescription drugs?
- *Secondary research question:* How, if at all, do names that suggest an overstatement of the degree of efficacy of the drug affect consumers' and/or healthcare providers' perceptions of prescription drugs?

The ideas generated in the Prescription Drug User Fee Amendments pilot project proprietary name review concept paper of 2008 [1] provided a starting point for the study.

[1] *https://www.regulations.gov/docket?D=FDA-2008-N-0281.*

Based on ideas from that document, a review of the linguistics and social sciences literature, and an environmental scan of existing proprietary names, FDA developed and pretested an extreme, explicitly suggestive name (*e.g.,* CuresFlux) and a neutral name (*e.g.,* Zerpexin) for two medical conditions, high cholesterol and gastroesophageal reflux disease (GERD) (pretesting approved under OMB control number 0910–0695). In the proposed main study, approximately 500 consumers from the general population and 500 healthcare providers (including physicians, nurse practitioners, and physician assistants) will see these pretested extreme and neutral names plus five target names per indication (names that may suggest the medical condition and vary in terms of promise of effect) and answer questions about the names, before and after they have been told what each drug's indication is. Target names will vary such that some efficacy implications are more apparent than others, and some will more clearly imply the medical condition for which a drug is indicated than others. Dependent variables will include identification of the medical condition for which a drug is indicated, efficacy, and perceptions.

To our knowledge, this study is the first to provide a systemic investigation of a variety of proprietary prescription drug names.

In the **Federal Register** of January 21, 2020 (85 FR 3392), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received seven submissions that were PRA-related. One submission was outside the scope of the research and is not addressed further. Within the remaining six submissions, FDA received multiple comments that the Agency has addressed below. For brevity, some public comments are paraphrased and therefore may not include the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. The following acronyms are used here: HCP = healthcare provider; FDA and Agency = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

(Comment 1) Two comments recommended that the study should exclude consumers who work in the healthcare, marketing, or branding industries; primary care providers that spend less than 50 percent of their time on patient care; and the Department of Health and Human Services employees.

(Response 1) We agree and currently have those exclusions included in the screener.

(Comment 2) Two comments recommended the screener should include additional inclusion/exclusion criteria, such as number of years in practice and in what size facility they work (HCPs), and whether consumers have any of five diagnoses and how many HCPs they see (consumers).

(Response 2) We plan to include most of the screening criteria and demographic data mentioned, including years in practice (HCPs); amount of time treating patients (HCPs); size of facility (HCPs); age (consumers); and diagnosis with one of the two illnesses which the hypothetical drugs in this study are indicated to treat—GERD and high cholesterol (consumers). Some of the other suggested questions for the screener are beyond the scope of this study. For this study, we have chosen to focus on primary care providers, as drugs for these two specific medical conditions are prescribed by primary care providers and should thus be salient for them. Additionally, we will ask relevant background questions of all participants, both HCPs and consumers, to determine age, sex, and race, as well as familiarity with the target conditions.

(Comment 3) One comment recommended that the complexity of the target names should be equivalent across indications.

(Response 3) We have attempted to make these as similar as possible, including having them reviewed by a linguist and checking the number of syllables across conditions.

(Comment 4) Three comments recommend better clarity around what the definitions of ''typical'' and ''standard'' and ''extreme'' and ''neutral'' mean when describing the fictitious drug name and how these categories were identified and validated.

(Response 4) The list of names was developed by our multimedia and creative services team who are well-versed in the practice of proprietary name development. The list was reviewed by the study team and also by a consultant with a Ph.D. in linguistics, who helped to screen for any overlap between categories.

In July 2019, we conducted a pretest of 120 healthcare providers and 121 consumers to establish the categories for these names. We combined results of four measures to determine the most extreme and most neutral amongst a list of names. These measures included ability to identify the medical condition for which the drug is indicated; perceived benefit and perceived balance of benefit and risk; and, finally, a ranking of most obvious benefit. Names with the lowest joint rank across the four measures were considered most extreme and those with highest were considered most neutral. The results were consistent between HCPs and consumers.

(Comment 5) One comment recommended excluding ''extreme, explicitly suggestive'' proprietary names that FDA would never permit or names that suggest the drug indication. The comment suggested instead that FDA use data that could assist the Agency in determining impressions produced by permissible proprietary names and names that would marginally fail FDA's misbranding review.

(Response 5) The purpose of including ''extreme'' names in this study is not to have data on names that do not mimic real-world conditions, but to have something against which to compare the target names, which are similar to the kind of names that would be submitted to FDA for approval. Our findings may suggest that ''extreme'' and target names are very different and that target names are similar to more neutral names in their effects on perceptions.

(Comment 6) One comment inquired if FDA will be providing sound files with the intended pronunciation of each of the test names.

(Response 6) In consideration of this comment, and after hearing from our cognitive interview participants, we will introduce sound files at the beginning of the survey.

(Comment 7) One comment expressed concerns about how the selection of target names will represent the current landscape—that is, it questioned how FDA will generalize these study results across therapeutic areas not tested if only representing one or two therapeutic areas.

(Response 7) We recognize that our study is making use of only two therapeutic areas. As one research study, it cannot examine all possible therapeutic areas. Although our two divergent medical conditions will not provide us with unlimited information, they will provide limited generalizability and provide important information that may help inform the proprietary name review process.

(Comment 8) Two comments were concerned that the questionnaire would take longer than the estimated 20 minutes.

(Response 8) See our response to Comment 4 concerning the pretest that we conducted in July 2019. In the pretest, we successfully tested a total of 16 names across two indications in this time frame. During cognitive testing, we

examined burden and decided to eliminate Q[uestion]7, which will speed response. We will also conduct a soft launch of the survey with approximately 10 percent of the sample and can look at actual length at that time. This gives us the ability to pause fielding of the survey and make further cuts if the soft launch data suggest it is necessary.

(Comment 9) Five comments recommended that we add ''none of the above,'' ''no impression,'' ''no opinion'' or ''do not know'' response options to some questions.

(Response 9) The rationale usually given for including ''don't know''/''no opinion''/''none'' options is to allow participants who cannot form a relevant judgment (*e.g.,* due to insufficient information) a way to indicate as much. However, an unintended consequence of including these options is that they can facilitate satisficing, where participants who have enough information to form a relevant judgment nonetheless choose ''don't know''/''no opinion''/''none'' because it takes less effort. As a result, ''don't know''/''no opinion''/''none'' options do not tend to improve measurement and tend to increase item nonresponse (*i.e.,* missing data) (Ref. 1). For these reasons, we will not add these options.

(Comment 10) Seven comments suggested adding more open-ended responses to explain why respondents answered questions in certain ways.

(Response 10) As noted by two comments the survey may be longer than an average of 20 minutes, which will cause us to remove questions after cognitive testing. Unfortunately, it is impractical to include many open-ended questions in this particular research because of time constraints. Qualitative research on this topic may be a good idea for a future study.

(Comment 11) One comment recommended checks to ensure that respondents are not being careless in their responses (*e.g.,* just guessing, providing random answers, straight-lining).

(Response 11) We intend to check for inattentive respondents by testing for straight-lining and examining the distribution of time to complete the study for outliers. Participants who complete the study plus or minus three standard deviations from the sample mean will be excluded from the main analysis. We agree with the recommendation to include speed traps/attention checks in the questionnaire and will add one to the study.

(Comment 12) Three comments requested access to the screener or study target names.

(Response 12) We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. 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. We strive to publish the results of our research in peer-reviewed journals and all stimuli will be available at that time.

(Comment 13) One comment recommended a specific approach for addressing the issue of broadening the indication that included an unaided ''fit to category'' question and an open-ended ''does the brand name tell you anything about the product?'' OR ''what does this name mean to you?''—type question for each name.

(Response 13) The approach described in this comment is one method to approach the issue of broadening the indication and may be useful for future research. However, in the current study we aim to collect information about multiple names, which precludes open-ended questions for each name in a single participant session. Moreover, our initial examination is focused on overstatement of efficacy. Broadening of the indication is another topic that researchers could pursue.

(Comment 14) One comment mentioned that we had no particular items on the issue of unique composition and suggested adding an open-ended question regarding general associations to determine whether a particular ingredient or dosage formulation is implied by a proprietary name.

(Response 14) Our current research is focused on the issue of overstatement of efficacy in proposed proprietary drug names. Future research could examine issues related to composition and dosage formulation, but that is beyond the scope of the current research.

(Comment 15) One comment suggested FDA should conduct two survey pretests: One to assess whether the survey answers the research questions, and one that allows respondents to complete the survey under the supervision of a moderator, who is able to converse with respondents and gather feedback on how participants interpret the questions. Further, the comment suggests FDA should consider conducting qualitative followup interviews with survey respondents to gain deeper insight into how the sample proprietary names affected their impressions of safety, efficacy and indication.

(Response 15) We have accomplished the goals recommended in this comment by conducting cognitive interviewing. During these cognitive interviews, participants were encouraged to think aloud as they reviewed and answered the survey with prompts from a trained moderator. These interviews enabled us to capture deeper, more qualitative responses from a small nonrepresentative sample of individuals in order to improve the questionnaire.

(Comment 16) One comment suggested FDA consider the inverse approach of our design by setting up the research to examine how, if at all, names that do suggest the drug's indication increase the chance for proper usage, reduce the potential for medication errors, do not mislead HCPs or patients regarding non-approved use of the drug, and increase the chance that if a patient does ask an HCP about a certain medication then that medication would be one approved to treat a condition with which the patient has been diagnosed.

(Response 16) The purpose of the current study is to provide evidence about whether certain types of names influence consumers' perceptions, as well as benefit and risk perceptions so that FDA reviewers may better assess names during premarket review. Other effects of names are beyond the scope of the current study but may be considered in future research.

(Comment 17) One comment suggested the ability of HCPs who prescribe drug products to determine whether a proprietary name overstates the efficacy of that product *without* the ability to review the respective package insert labeling fails to meet the intent of 21 U.S.C. 321(n). The comment further stated that OPDP and the sponsor of the product are in the best position to determine the relationship between the proprietary name and the material facts in the labeling of the product, which sometimes is not available at the investigational new drug (IND) application stage when proprietary names are developed and tested with consumers and HCPs.

(Response 17) The purpose of the current study is to determine whether a proprietary name itself could play a role in influencing consumer and HCP perceptions of drug risks or benefits by suggesting the medical condition for which the drug is indicated or by suggesting an overstatement of the efficacy of the drug. Including the package insert would confound any potential results of this study, as it would not be possible to tease apart

whether perceptions were influenced by the name itself or the accompanying materials. We note that this is a large-scale study examining multiple names and that our purpose in conducting it differs from that of a pharmaceutical company engaged in developing and testing the proprietary name of one of its products.

(Comment 18) One comment suggested that the proposed primary research question, which is designed to determine how, if at all, a proprietary name that suggests the medical condition for which it is indicated affects perceptions of the drug, does not determine whether a name overstates the efficacy of the product.

(Response 18) We agree that whether a name suggests the medical condition for which a drug is indicated is a separate question from whether the name overstates the drug's efficacy. However, we aim, in part, to investigate how individuals perceive the efficacy of products when the names do suggest the medical condition they are indicated to treat. The purpose of this study is to compare names that: (1) With varying degrees of specificity, may suggest the medical condition for which a drug is indicated, with or without varied promises of effect (target names); (2) we know through pretesting overstate the efficacy (extreme names); and (3) we know to be neutral through pretesting. Perceptions of consumers and HCPs are important to consider when reviewing proprietary names and thus, important to test empirically.

(Comment 19) One comment suggested that research is not necessary because names should be evaluated by those who have medical and regulatory experience.

(Response 19) We agree that people who are knowledgeable about the relevant fields should make decisions about proprietary names based on the best information in their fields. Determining how names are processed and understood by consumers and HCPs is important information to be considered in the review of these names. Therefore, this research is being conducted to increase the body of evidence upon which experts can rely when assessing proposed proprietary names for misbranding concerns.

(Comment 20) Three comments mentioned the study sample size. One comment stated that the reason for selecting approximately 1000 respondents was not provided, and it suggested that the size of such a study on a proposed drug product would not be reasonable or cost effective for the pharmaceutical industry. One comment recommended that an appropriate sample size be used, and another comment remarked that the sample size seemed appropriate.

(Response 20) The sample size was selected based on power analysis. We have set statistical power for the main study to test five proposed names against both the neutral control name and the extreme control name, using a 7×7 Latin squares design. With a Bonferroni correction for up to 10 pairwise comparisons, the study is powered to detect conventionally small effects ($f \geq 0.06$, $dz \geq 0.21$, or 0.14 difference in proportions) assuming a family-wise alpha level of 0.005 and 90 percent power for all tests.

This is a large-scale study examining multiple names, whose purpose differs from that of one pharmaceutical company assessing their chosen names.

(Comment 21) One comment concurred that an automated online survey would be the most efficient means to conduct the research.

(Response 21) Thank you for this comment.

(Comment 22) One comment asked that we clarify what specific statistical tests will be performed to determine whether a particular target name has an improper (biasing) impact on perceptions of drug efficacy and/or safety—and (possibly) on other perceptions.

(Response 22) To compare names based on the categorical name recognition and perceived indication questions, we will apply nonparametric tests of dependent proportions. First, we plan to conduct Cochran's *Q* test separately for each list of names, testing whether the proportions of at least two names per list are significantly different from one another. We will follow up significant Cochran's *Q* tests with McNemar's pairwise tests, comparing each target name against the neutral and extreme names in each list.

To test for evidence of mean differences by drug name on interval-level outcomes (*e.g.,* perceived efficacy magnitude, perceived severity of risks, and perceived balance of risks and benefits), we will use repeated-measures analyses of variance or mixed model analysis. We will run separate models for each list of names and study cohort. We will follow-up significant omnibus tests by conducting pairwise comparisons between each of the target names versus the neutral and extreme names.

See information about the study's statistical power assumptions above.

(Comment 23) One comment asked for clarity regarding what decision rule or norm/standard will be used to conclude that there is or is not improper suggestiveness.

(Response 23) There is an important distinction between investigating the effect of a prescription drug name on perceptions and establishing that the name is improperly suggestive. This study is focused on the effect on perceptions of: (1) Names that suggest the medical condition for which a drug is indicated with varying degrees of explicitness and (2) names that suggest an overstatement of the efficacy of the drug with varying degrees of explicitness. Determining whether what a prescription drug name suggests or the name's degree of suggestiveness is ''improper,'' or could contribute to misbranding the drug or to other violation(s) of the FD&C Act and Agency regulations, falls beyond the scope of the current project.

(Comment 24) One comment suggested clarifying the purpose and intended use of the data and further suggests that regardless of the purpose of the proposed information collection, in addressing use of the survey data, FDA should account for the First Amendment protection provided to proprietary names.

(Response 24) As stated in the 60-day notice, the purpose of this study is to expand the body of knowledge by answering questions about whether names alone impact consumer and provider perceptions of a drug. This information will help inform the proprietary name review process. FDA's review of proprietary names is conducted to help ensure that proposed proprietary names do not contribute to misbranding a drug or to other violation(s) of the FD&C Act and Agency regulations, particularly when that proprietary name appears in labeling (see, *e.g.,* 21 U.S.C. 321(n) and 352(a)). We conduct our review of proprietary names in accordance with applicable legal authorities, including the First Amendment.

(Comment 25) One comment suggested Q1 should have a timer element (*i.e.,* 15–20 seconds) for each set of seven names that will help to standardize the time spent by viewers on both sets and mitigate viewers who would quickly scan Set 1, only to spend more time on Set 2 after realizing they will be asked to recognize the names.

(Response 25) In addition to counterbalancing the sets of names, we will institute a time limit for each viewing.

(Comment 26) Another comment suggested that for Q1, we use names that were found unacceptable due to promotional reasons for foils.

(Response 26) The purpose of Q1 is to determine how well participants recall the names they viewed. The foils are used to help determine whether participants are merely checking off the complete list of names or marking ones they truly saw on the previous screen. Thus, we do not believe using actual names as foils would add value.

(Comment 27) One comment mentioned that Q3–Q7 introduce an aided portion of the survey (by grouping names into two specific medical conditions and identifying those names with each medical condition to the respondents) and suggested that, without seeing the product profile, ''it will be difficult to get responsible data on efficacy perceptions of the respondents.'' Another comment suggested that Q3 should ask a more specific question, perhaps on unique effectiveness or overstatement of efficacy.

(Response 27) Our research questions focus on whether the names alone result in perceptions of risk or efficacy, thus, Q3–Q7 are directly relevant to the research questions. Regarding Q3, we do not want to lead participants into answers or confuse them by asking them about regulatory terms with which they are unfamiliar. We will delete Q7.

(Comment 28) Regarding Q2, one comment suggested caution in terms of handling responses in which respondents presented with a particular target name (*e.g.,* ''AltAFlux'') fail to identify the indication that the name is hypothesized to be suggestive of (*e.g.,* ''Acid Reflux''), checking another indication instead (*e.g.,* ''Asthma''). In such cases, it would be inappropriate to interpret any observed effects on drug perceptions to the name being overly suggestive of a particular indication. A conservative course of action would therefore be to remove from subsequent analyses all instances in which a target name is not attributed to its hypothesized indication.

(Response 28) The target names are representative of the types of names that are frequently submitted to FDA for review. They may include information about the medical condition for which the drug is indicated, or both the medical condition and efficacy. We do not presuppose that a name's effect on perceptions of drug effectiveness are dependent on recognition of the medical condition for which the drug is indicated, though we will consider this mediation effect as we refine the analysis plan for this project.

(Comment 29) One comment suggested that Q4 does not seem relevant since serious side effects of the drug would normally be evaluated in the context of the clinical studies or post-marketing studies and would be presented in the package insert labeling.

(Response 29) The question is whether the name alone influences perception of risk and benefit; thus, Q4 is directly relevant to answering those questions.

(Comment 30) Three comments suggested deleting Q5. For example, one comment discussed that perceived balance of risks and benefits is usually communicated in advertising by utilizing the approved labeling in presenting fair balance and, thus, a proprietary name would not normally present risks and benefits. The comment stated that names that do present benefits within the name without context to its risk would not be considered misleading since the approved labeling would represent balance of risks and benefits.

(Response 30) Our research questions focus on whether the proprietary name alone affects consumer and HCP perceptions of risk or efficacy of the drug. Q5 helps to answer those research questions by asking participants to opine on whether the proprietary name alone indicates to them that the benefits of a product outweigh the risks. Our research will not answer the question whether a given name is misleading or whether labeling or advertising incorporating the name would violate the FD&C Act and its implementing regulations.

(Comment 31) One comment suggested that measuring attitudes toward each name (Q6) does not seem to add anything toward measuring the efficacy claims of a name and another comment recommends changing semantic differential endpoints for this item.

(Response 31) Measuring attitudes adds to our knowledge of how individuals interpret particular drug names. The semantic differential endpoints used in the original attitude question, as well as the proposed replacements, are among those recommended by prominent attitude theorists (Ref. 2). We have used these items in several studies without any issues, including studies measuring consumer and physician attitudes toward prescription drugs. Nevertheless, we will replace the negative-positive item with an item using worthless-valuable as endpoints.

(Comment 32) Five comments suggested reducing or eliminating Q7, which questions participants about their attitudes toward the drug names.

(Response 32) As noted in Response 17, in the interest of reducing time burden for participants, we will delete this question.

(Comment 33) Two comments questioned the utility of or recommended deleting Q8.

(Response 33) We agree and will delete this item.

(Comment 34) Two comments suggested that Q9 and two comments suggested that Q10 and Q11 are not applicable to the objectives of this survey.

(Response 34) Similarity, typicality, and familiarity could reasonably influence perceptions of drug names independently of the experimental manipulation. These measures are being included in this study as potential covariates.

(Comment 35) One comment suggested that Q11 is confusing, as respondents are asked to rate if they ''have heard of each of the following drug names before,'' after being previously told in the questionnaire introduction that the drugs ''have been recently developed'' and before being informed in the debriefing that the names are fictitious. Moreover, some respondents could interpret the present question as meaning ''Were the following names mentioned in this survey?'' which is presumably not the intent of the question.

(Response 35) We agree that this item as written was confusing, and this was confirmed by cognitive testing. Thus, we will alter the question to clarify that we are interested in whether respondents had heard the drug name prior to the study. This question will be used as a covariate in the study design.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Consumer Screener	1,233	1	1,233	.08 (5 minutes)	98.64

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
HCP Screener	1,233	1	1,233	.08 (5 minutes)	98.64
Consumer Study	493	1	493	.33 (20 minutes)	162.69
HCP Study	493	1	493	.33 (20 minutes)	162.69
Total					522.66

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

References

The following references are on display with the Dockets Management Staff, HFA–305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852, 240–402–7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; these are not available electronically at *https://www.regulations.gov* as these references are copyright protected. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Krosnick, J.A. and S. Presser, ''Question and Questionnaire Design.'' In P.V. Marsden and J.D. Wright (Eds.). *Handbook of Survey Research* (2nd Ed.). Emerald: Bingley, UK, 2010.
2. Fishbein, M. and I. Ajzen, *Predicting and Changing Behavior: The Reasoned Action Approach*. New York, NY: Psychology Press, 2010.

Dated: March 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–E–0340]

Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM

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 HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

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 May 17, 2021. 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 September 13, 2021. 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 May 17, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 17, 2021. 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–2020–E–0340 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; HINTERMANN SERIES H3 TOTAL ANKLE REPLACEMENT SYSTEM.'' 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