for the operation of both businesses and their employees. Both Anchor Foods companies were located in Westbury, New York.

From on or about February 2011 and continuing through January 2014, Mr. Tuccillo knowingly and willfully conspired with Anchor Foods, Roy Tuccillo, Jr., and others to import giant squid from Peru to Mr. Tuccillo's companies' location in Westbury, New York and repackage and sell that squid falsely labeled and identified as ''octopus.'' Mr. Tuccillo sold the falsely labeled squid in interstate commerce to grocery stores in New Jersey, Texas, and Massachusetts. Mr. Tuccillo used email and fax to sell and receive payments for the squid falsely labeled as octopus. In total, Mr. Tuccillo's companies made $1,128,388.50 worth of fraudulent sales of squid.

As a result of this conviction, FDA sent Mr. Tuccillo, by certified mail on June 6, 2022, a notice proposing to debar him for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Mr. Tuccillo's felony conviction of conspiracy to commit wire fraud in violation of 18 U.S.C. 371 and 1343, constitutes conduct relating to the importation into the United States of an article of food because Mr. Tuccillo knowingly and willfully conspired with Anchor Foods, Roy Tuccillo, Jr., and others to import giant squid from Peru to his companies' location in Westbury, New York and repackage and sell that squid falsely labeled and identified as ''octopus'' in interstate commerce, using email and fax to sell and receive payments for the falsely labeled squid. The proposal was also based on a determination, after consideration of the relevant factors set forth in section 306(c)(3) of the FD&C Act (21 U.S.C. 335a(c)(3)), that Mr. Tuccillo should be subject to a 5-year period of debarment. The proposal also offered Mr. Tuccillo an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Mr. Tuccillo failed to respond within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and waived any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(1)(C) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Tuccillo has been convicted of a felony count under Federal law for conduct relating to the importation into the United States of an article of food and that he is subject to a 5-year period of debarment.

As a result of the foregoing finding, Mr. Tuccillo is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, applicable (see **DATES**). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Roy Tuccillo, Sr., is a prohibited act.

Any application by Mr. Tuccillo for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA–2022–N–0316 and sent to the Dockets Management Staff (**ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20710 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1050]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Targeted Mechanism of Action Presentations in Prescription Drug Promotion

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: Submit written comments (including recommendations) on the collection of information by October 24, 2022.

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 ''Targeted Mechanism of Action Presentations in Prescription Drug Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

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

For copies of the questionnaire: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@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.

Targeted Mechanism of Action Presentations in Prescription Drug Promotion

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 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: 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 will inform the first two topic areas, advertising features and target populations.

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.

In 2014, OPDP conducted focus groups designed to provide insights on how consumers and healthcare providers (HCPs), including physicians, nurse practitioners, and physician assistants, interpret the term ''targeted'' in prescription drug promotional materials. Although diverse views were voiced, there appeared to be some tendency toward the impression that products with promotional materials using this term would be safer and more effective than other similar treatments. OPDP is also now conducting a nationally representative survey regarding the ways in which consumers and primary care physicians (PCPs) interpret terms and phrases commonly used in prescription drug promotional materials, including assessment of impressions of the terms ''targeted'' and ''targeted mechanism of action'' (targeted MoA) (86 FR 24867, May 10, 2021). Building upon this line of research, the proposed study will investigate the influence of targeted MoA claims, graphics, and disclosures that provide context about a drug's targeted MoA, utilizing an experimental design with both consumer and HCP samples. The experimental approach described here is intended to complement and augment the prior research by facilitating assessment of causality. Specifically, the proposed study will explore how varied targeted MoA presentations affect consumer and HCP understanding of the MoA of a drug, perception of drug benefits and risks, attention to risk information, and interest in the drug.

Table 1 depicts the study design. Participants will be randomly assigned to one of 12 experimental conditions in which the presence versus absence of: (1) a targeted MoA claim, (2) a graphic depicting a targeted MoA, and (3) a disclosure that provides context about the targeted MoA of the drug are varied in a branded website for a fictitious prescription drug indicated to treat bladder cancer and cancers of the urinary tract (renal pelvis, ureter, or urethra) that have spread or cannot be removed by surgery. We selected cancer as the medical condition for study given the prevalence of targeted MoA presentations in promotional materials for prescription drugs indicated to treat various forms of cancer. Notably, there will be three variations related to the targeted MoA graphic: (1) no graphic, (2) an inaccurate graphic (graphic 1) showing only the effect of the drug on cancerous cells but not on healthy cells, and (3) an accurate graphic (graphic 2) that will show the effect of the drug on both cancerous and healthy cells. The design will be replicated in both the consumer and HCP samples with stimuli specifically created for each audience. Draft stimuli were informed by, but not identical to, actual targeted MoA presentations from a marketplace evaluation conducted under FDA guidance. Draft stimuli were also informed by an FDA subject matter expert's review. Following exposure to the stimuli, the participants will complete a questionnaire designed to assess relevant outcome measures. A copy of the questionnaire is available upon request. All aspects of this study will be completed online. Participation is estimated to take approximately 20 minutes, excluding the screener's time.

TABLE 1—STUDY DESIGN

Sample	Disclosure	Targeted MoA claim	Targeted MoA graphic		
			Present (graphic 1—inaccurate)	Present (graphic 2—accurate)	Absent
HCP	Present	Present	[1] ■	■	■
		Absent	■	■	■
	Absent	Present	■	■	■
		Absent	■	■	■
Consumer	Present	Present	■	■	■
		Absent	■	■	■
	Absent	Present	■	■	■
		Absent	■	■	■

[1] Each ■ symbol represents an experimental condition.

For the HCP sample, we will recruit oncologists, PCPs with oncology experience, and nurse practitioners and physician assistants who specialize in oncology. We will also recruit a general population sample of adult volunteers 18 years or older for the consumer sample. A general population, rather than a diagnosed consumer sample, was selected because of concerns about being able to recruit enough participants for this particular study if we selected a cancer-specific sample.

We will ask consumers to consider a hypothetical scenario in which they have recently been diagnosed with cancer and are actively looking for available treatments. HCPs will be asked to consider a scenario in which they are actively looking for available treatments for a patient who has been diagnosed with cancer. We will also ask consumers if they have ever been diagnosed with cancer. HCP participants will be drawn

from online HCP panels, and general population consumer participants will be drawn from online consumer panels. Informed by power analyses, we will recruit a sample of 540 HCPs and 540 consumers for the main study.

In the **Federal Register** of October 28, 2021 (86 FR 59736), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received five comments that were Paperwork Reduction Act (PRA) related. Within the submissions, FDA received multiple comments that the Agency has addressed in this notice. For brevity, some public comments are paraphrased and, therefore, may not state the exact language used by the commenter. All comments were considered even if they were not fully captured by our paraphrasing in this document. One submission (ID number FDA–2021–N–1050–0002) was read and considered but was outside the scope of the research and is not addressed further. Comments and responses are numbered here for organizational purposes only.

(Comment 1) One comment stated that FDA has already investigated how HCPs and consumers interpret the terms ''targeted'' and ''targeted mechanism of action.''

(Response 1) Prior qualitative research [1] looked at how consumers and HCPs interpret the term ''targeted'' in prescription drug promotional materials. This initial qualitative research suggested that products using the term ''targeted'' may appear safer or more effective than other similar treatments but did not fully explore the implications of those interpretations. Robust empirical evidence is needed to understand how complex concepts, such as ''targeted'' and ''targeted MoA,'' are interpreted or whether they lead to inaccurate inferences about a drug's efficacy and side effects when presented to consumers and HCPs in prescription drug promotion. The present research seeks to extend previous studies by investigating the effects of including a graphic and by exploring whether the inclusion of a disclosure statement can help to clarify the information. It is possible that the presence of targeted MoA graphics affects the impressions of the product, which we are assessing in this study. It is also possible that any inflated perceptions consumers or HCPs may have based on the MoA claim or graphics can be adjusted by adding a disclosure. These are the questions this research is aiming to address through an experimental design. We conducted a literature review, which found that only two published articles (Refs. 1 and 2) have focused on assessing the impact of exposure to MoA presentations in prescription drug promotion. We also conducted a marketplace evaluation, which found that these types of presentations are widespread in the prescription drug promotion marketplace. Together, this preliminary work highlights the importance of this study and the need for experimental research that examines the effect of targeted MoA presentations in prescription drug promotion on both consumers and HCPs.

(Comment 2) Two comments proposed recruiting cancer patients rather than general population consumers because, according to one comment, cancer patients are more likely to be exposed to promotional materials regarding cancer products and may be more familiar with cancer-related terms than the general population. The comments also suggested that being diagnosed with a life-threatening illness may influence perception of risk/benefit and interest in a drug. One comment encouraged the Agency to look for ways to mitigate such bias, and the other specifically proposed that the Agency focus the research on a target consumer respondent sample of those who have had a cancer diagnosis and allow the screening criteria to straddle across multiple cancer diagnoses.

(Response 2) We chose a general population sample because of concerns about being able to recruit enough participants if we selected a cancer-specific sample. However, we agree that in a future study, a small, carefully designed replication study with cancer patients could be valuable. We will also ask participants if they have been diagnosed with cancer and control for any impact that a diagnosis of prior cancer may have.

(Comment 3) One comment objected that access to the specific study stimuli and questionnaire was not provided.

(Response 3) We have described the purpose of the study, the design, and the population of interest and have provided the questionnaire to numerous individuals upon request. We provided the disclosure language in the questionnaire. 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 our research.

(Comment 4) Two comments suggested that the research assumes that all targeted MoA claims that do not include a discussion of off-target effects are misleading and that it is misleading to suggest that targeted therapies are safer or more effective. The comments noted that this assumption would be overly broad and simplified and may result in biased results.

(Response 4) This research does not assume that any specific presentation is or is not misleading. Rather, this research aims to understand whether variations in MoA presentations of a targeted drug (*e.g.,* presenting an inaccurate graphic depicting a drug's MoA without a disclosure relative to an accurate graphic depicting the MoA) may affect consumer and HCP perceptions of the drug. In this way, the research will provide more information to help determine whether these audiences are misled by the tested presentations.

(Comment 5) Two comments focused on the proposed graphics. One expressed concern about the ability of a graphic to depict a targeted MoA accurately (particularly as it refers to the impact on off-target healthy cells) and to convey a truthful and non-misleading representation. The other comment proposed changes to the inaccurate graphic in terms of how it depicted healthy and cancer cells.

(Response 5) We tested candidate graphics in cognitive interviews to confirm that the audience interpreted the graphics as intended. The graphics were also reviewed by medical professionals, and we consulted with a doctoral-trained researcher who publishes extensively on the effects of graphic presentations in health communication and advertising.

(Comment 6) One comment noted that it is unclear what proportion of the sample will be oncologists versus PCPs with oncology experience. The comment also stated that while PCPs may have a role in the cancer patient's journey and may provide input along the way to diagnosis, as well as during the management phase of treatment, they are not routine decision makers for new treatments or treatment changes.

(Response 6) HCPs of all types are exposed to prescription drug promotion. Depending on location (*e.g.,* rural areas) and type of clinical setting, some non-oncologists may consider oncologic prescription drugs to treat their patients. We agree that oncologists are the most relevant population to study in this research. However, we also want to know whether specific education and experience influence the processing of claims, graphics, and disclosures. We

[1] See ''Focus Groups to Investigate Specific Terminology in Prescription Drug Promotion (completed in 2014),'' available at *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.*

intend to use PCPs as a control group to understand whether specific advanced training influences the understanding of MoA claims, graphics, and associated disclosures. Further, including PCPs with oncology experience alongside oncologists has yielded useful data in prior studies (Ref. 3). The sample will be equally distributed across oncologists, PCPs with oncology experience, and nurse practitioners and physician assistants with oncology experience.

(Comment 7) One comment stated that the study should only recruit nurse practitioners and physician assistants who specialize in oncology.

(Response 7) We agree. Only nurse practitioners and physician assistants who specialize in oncology are eligible for the study.

(Comment 8) One comment noted that the instructions at the top of the questionnaire ask participants to ''make your best guess'' based on the web page they just viewed. The comment stated that respondents should not be asked to guess as their response and argued that these instructions undermine the importance of the participants' answers.

(Response 8) The instructions are displayed before perceived efficacy and risk questions where consumer participants are told, ''Most people don't know how a prescription drug will affect them until they've taken the drug. But we'd like you to make your best guess based on the web page you just saw. Please answer the following questions based on what you saw on the web page.'' HCPs are told, ''Please answer the following questions based on what you saw on the web page rather than prior knowledge of this class of medications.''

These instructions have been cognitively tested in prior studies, as well as in the present study, and we found no evidence that these instructions undermined the perceived importance of participants' answers. Instead, the instructions helped to indicate that we wanted participants to form an opinion and that they did not need to base their opinion on prior knowledge to do so.

(Comment 9) One comment suggested that the recall questions (questions 6 through 11) and especially the ''foil'' responses could bias the responses to the questions that follow them and recommended locating the recall questions after other questions.

(Response 9) We always approach question ordering carefully, attempting to balance several considerations, including the reduction of bias from one question to another, the flow, and the importance of each item. In this case, we are prioritizing measures of specific claim comprehension over other more general questions in our questionnaire, which is why questions 6 through 11 are placed earlier in the questionnaire. Answering recall and comprehension questions first will allow consumers and HCPs to provide a more accurate response and will allow us to better understand whether the information was comprehended. We did not encounter any issues with recall questions influencing responses to questions found later in the survey during cognitive interviews.

(Comment 10) One comment recommended using a consistent scale throughout the survey. Another suggested changing questions 12, 13, 14, 16, 17, 18, 19, 20, 22, and 23 to 7-point scales to add a midpoint.

(Response 10) We use true/false/don't know or yes/no/don't know response options for the comprehension questions and Likert-type scales for perceptions and opinion questions. Using one scale throughout the survey would not necessarily provide better data. For nearly all Likert-type questions, we use 6-point scales with the endpoints labeled. Some of these questions with Likert-type scales are validated questions; for these, we have maintained the response options from the validated measures. Other questions were altered from validated measures, and similarly, we preferred to maintain the Likert-type scales that the original measure had. We will change question 5 from a 7-point to a 6-point scale to increase consistency. We will retain the 5-point scales with all response options labeled for the two validated scales for beliefs about medications and trust in prescription drug materials.

Regarding the inclusion of a midpoint, this is a matter of debate in the literature and has never been resolved. Based on input from cognitive interviews and in response to public comments, we will be adding a neutral point to the comparative efficacy and risk questions (*i.e.,* questions 17 through 23), which will change these questions to be 7-point response options with endpoints and midpoint labeled.

(Comment 11) Two comments stated that the 6-point scales do not allow the respondent to pick neither agree/disagree/unknown. One comment noted that this is a concern for most 6-point scale questions but particularly for questions 17 through 23, which compare the study drug to other medications. The comments recommended either an anchored neutral middle point on the scale or a box for uncertain/do not know responses.

(Response 11) There are benefits and drawbacks to including a neutral or ''no reaction'' response in survey research, and the decision to use a neutral midpoint depends on the goal of the measures (Refs. 4 and 5). For questions assessing comprehension of the MoA claim, we included a ''do not know'' option as this response would indicate some level of uncertainty about the MoA, and that uncertainty itself would be meaningful and actionable information. However, when assessing perceptions and attitudes about the claim, graphic, or disclosure, our objective is to force a selection. Inclusion of a neutral response option in these instances could potentially encourage satisficing—cuing participants to select a neutral response when there is uncertainty (Ref. 7). For the comparative risk and efficacy questions (questions 17 through 23), we will include a midpoint based on results from cognitive interviews; however, these interviews did not point to the need to include a midpoint for the other questions.

(Comment 12) Questions 17 through 23 ask about the efficacy and risks of the study drug compared to other prescription drugs for the same indication. One comment contended that, without prior knowledge of the efficacy and risks of the prescription drugs on the market, it would be difficult for respondents to make a fully informed conclusion. Another comment asserted that the comparative risk and efficacy questions should be revised to establish a clear comparator, such as chemotherapy. Finally, a comment recommended removing these questions as consumers should not be assessing a drug's safety or efficacy compared to other drugs.

(Response 12) There are instances in the clinical setting when consumers will discuss the safety and risk information of a drug compared to others (*e.g.,* if a patient switches from one drug to another or if a family member asks the consumer to talk to their doctor about another drug). We acknowledge that in a clinical setting, patients and HCPs may use additional information to make decisions about how a drug compares to another. However, the intent of questions 17 through 23 is to understand whether exposure to different presentations of the MoA claim, graphics, and disclosure results in different comprehension or perceptions, such as perception of comparative risks and efficacy. Except for the varied presentations, all participants will have the same level of information regarding the MoA of the drug. So, we would expect that all

participants would be equally informed of the drug, and differences among study conditions could be attributed to the experimental manipulations. Additionally, any subjective experiences outside the experiment setting should be evenly distributed across study conditions as a function of random assignment; therefore, they should not have any impact on the outcomes of the study. Still, cognitive interviews indicated that HCPs and consumers preferred that a midpoint be added to the response scale for these questions, which we added in the revised questionnaire. Based on cognitive interviews, we also revised the questions to include the phrase ''compared to other similar prescription drugs that are for/treat bladder cancer.'' We will also review these questions and make any necessary adjustments based on pre-testing results.

(Comment 13) One comment stated that the questionnaire does not consider the HCP respondents' baseline understanding or expectations of targeted treatments.

(Response 13) We expect that any knowledge or expectations of targeted treatments that consumers and HCPs already have outside of the experiment setting should be evenly distributed across study conditions as a function of random assignment; therefore, observed differences between conditions are unlikely to be caused by these individual differences. However, we added an item that assesses HCPs' knowledge of targeted therapies for cancer treatments.

(Comment 14) One comment encouraged FDA to disseminate all final results of completed research related to this topic.

(Response 14) FDA's research is documented on our homepage, 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. The Agency also anticipates disseminating the results of this study after the final analyses of the data are completed. The exact timing and nature of any such dissemination has not been determined, but dissemination of research results often occurs through presentations at trade and academic conferences, publications, articles, and postings on FDA's website.

(Comment 15) One comment recommended that certain populations, such as those who work in pharmaceutical marketing or for the U.S. Department of Health and Human Services (HHS), be excluded from the study.

(Response 15) We agree. Participants will be excluded from participation if they work for a pharmaceutical, advertising, or market research company or are employed by HHS.

(Comment 16) One comment recommended that participants who are unable to recall key elements of the stimuli, such as indication, risk elements, presence of claim, and presence of disclaimers, be excluded from the study because they are not able to appropriately assess the MoA presentations.

(Response 16) The fact that a consumer or HCP is not able to recall certain information does not mean they did not see that information or subconsciously process it (Ref. 6). Therefore, we do not plan to exclude anyone based on their self-reported recall of elements in the stimuli.

(Comment 17) One comment suggested that participants should be asked questions 30 through 34 as part of a pre-test and be stratified based on their responses.

(Response 17) Typically, stratified randomization is used if there are prognostic variables that correlate with outcome measures and researchers are concerned about such factors not being evenly distributed across groups (Ref. 8). We have no reason to expect that the aforementioned factors would have a strong association with the outcome measures, nor do we have reason to believe that we will not achieve adequate balance of prognostic variables given the large sample size proposed for this study (Ref. 8). Random assignment will help to produce groups that are, on average, probabilistically similar to each other. Because randomization eliminates most other sources of systematic variation, we can be reasonably confident that any effect that is found is the result of the intervention and not some preexisting differences between the groups (Ref. 9). However, we have included questions 30 through 34 to assess the association of factors such as health literacy, prior cancer diagnosis, or familiarity with cancer treatment options with our outcomes and statistically control for those variables if necessary.

(Comment 18) One comment suggested that in order to ensure that differences in risk assessment across stimuli are due to the manipulation of MoA information, the prominence of the risk presentation should be standardized across the 12 versions of the stimuli and displayed in accordance with FDA's guidance document entitled ''Presenting Risk Information in Prescription Drug and Medical Device Promotion.'' [2] The comment also encouraged the use of qualifiers to delineate which side effects are considered serious.

(Response 18) In creating the stimuli, we created one web page that was the basis for all the stimuli. The risk presentation was standardized across the experimental conditions, and we kept FDA's guidance in mind when displaying stimuli. Regarding the suggested use of qualifiers to delineate which side effects are considered ''serious,'' we again note that we kept FDA's guidance in mind with respect to the risk presentation.

(Comment 19) One comment noted that the disclosure for patients should be reworded as follows to prevent implied bias: ''[Drug X] delivers medicine directly to cancer cells and can also harm healthy cells.''

(Response 19) We revised the statement to read ''[Drug X] could also affect healthy cells.'' With this change, the consumer disclosure is consistent with the content of the disclosure shown to HCPs.

(Comment 20) One comment asserted that most promotional materials in the real world qualify MoA statements with language mirroring the labeling (*e.g.,* ''Pre-clinical studies demonstrate . . .'') and recommended that the research materials be updated to include similar qualifying language.

(Response 20) The addition of such language may create an imbalance of information across the various experimental conditions and could confound interpretation of the results. As such, we did not include the qualifying language mentioned above.

(Comment 21) One comment suggested that study participants should be allowed to refer back to the product website as often as needed rather than only being permitted to view it once.

(Response 21) As a practice, we often purposely do not permit study participants to refer back to the product website as often as needed for these types of studies. Rather, for this study, we will instruct participants to read the website carefully and alert them that they will be answering several questions about the content that they just saw and that they cannot return to the website. The goal of this study is not to assess participants' comprehension of verbatim information in the stimuli, for which

[2] The draft guidance for industry ''Presenting Risk Information in Prescription Drug and Medical Device Promotion'' (May 2009) is available on the FDA guidance web page at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* When finalized this guidance will represent FDA's thinking on this issue.

repeated exposures to stimuli may be more appropriate in another study. Rather, the present study is interested in gist understanding of the information. Allowing for multiple exposures to the stimuli could potentially influence study outcomes and confound interpretation of the study results. A large literature supports presence of a ''mere exposure effect'' in social science research, where more exposure enhances processing and increases positive affect toward stimuli (Refs. 10 and 11).

(Comment 22) One comment recommended removing question 16 (*i.e.,* risk-benefit tradeoff) for consumers because consumers may not have the experience or background to assess a drug's benefit-risk profile. The comment also suggested that this question ignores the role of prescribers in informing patients of the relevant risks and benefits of prescription medications.

(Response 22) We disagree that consumers do not form their own perceptions about risk-benefit tradeoffs after seeing direct-to-consumer (DTC) promotional materials and before any discussion with an HCP. Consumers often wish to participate in shared decision making with HCPs when selecting prescription drugs and may request specific prescription drugs from their HCPs based on promotions they have seen in the marketplace. Because the information consumers receive through DTC prescription drug promotion can impact these requests, it is important to investigate how the information in prescription drug promotional pieces impacts consumer attention, understanding, and perceptions. In addition, the purpose of these questions is to assess perceived benefit and risk based on the promotional material shown. The question includes instructions indicating that judgments should be reached based on the information on the prescription drug website. As such, we plan to ask participants about their perceptions of the risk-benefit tradeoff using question 16, which is a common and validated item in DTC research.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents [2]	Number of responses per respondent	Total annual responses	Average burden per response [3]	Total hours
Pretest:					
General population: pretest screener completes (assumes 75% eligible).	528	1	528	0.08 (5 min.)	42.2
General population: number of completes, pretest	396	1	396	0.33 (20 min.)	130.7
HCP: pretest screener completes (assumes 60% eligible).	660	1	660	0.08 (5 min.)	52.8
HCP: number of completes, pretest	396	1	396	0.33 (20 min.)	130.7
Main Study:					
General population: number of main study screener completes (assumes 75% eligible).	792	1	792	0.08 (5 min.)	63.4
General population: number of completes, main study	594	1	594	0.33 (20 min.)	196.0
HCP: number of main study screener completes (assumes 60% eligible).	990	1	990	0.08 (5 min.)	79.2
HCP: number of completes, main study	594	1	594	0.33 (20 min.)	196.0
Total	.....	.....	.....	.....	891

[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.

[3] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. O'Donoghue, A.C., Williams, P.A., Sullivan, H.W., et al. ''Effects of Comparative Claims in Prescription Drug Direct-to-Consumer Advertising on Consumer Perceptions and Recall.'' *Social Science & Medicine,* 120:1–11, 2014.

*2. Sullivan, H.W., O'Donoghue, A.C., Gard Read, J., et al. ''Testimonials and Informational Videos on Branded Prescription Drug websites: Experimental Study to Assess Influence on Consumer Knowledge and Perceptions.'' *Journal of Medical internet Research,* 20(1):e13, 2018.

3. Boudewyns, V., O'Donoghue, A.C., Paquin, R.S., et al. ''Physician Interpretation of Data of Uncertain Clinical Utility in Oncology Prescription Drug Promotion.'' *The Oncologist,* 26(12):1071–1078, 2021.

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6. Shapiro, S. and Krishnan, H.S. ''Memory-Based Measures for Assessing Advertising Effects: A Comparison of Explicit and Implicit Memory Effects.'' *Journal of Advertising,* 30(3):1–13, 2001.

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8. Friedman, L.M., Furberg, C.D., DeMets, D.L., et al. *Fundamentals of Clinical Trials.* 5th ed. New York, NY: Spring Science-Business Media, 1998.

9. Fisher, R.A. *The Design of Experiments.* Edinburgh, United Kingdom: Oliver & Boyd, 1935.

10. Bornstein, R.F. ''Exposure and Affect: Overview and Meta-analysis of Research, 1968–1987.'' *Psychological Bulletin,* 106(2):265–289, 1989.

11. Bornstein, R.F. and D'Agostino, P.R. ''The Attribution and Discounting of Perceptual Fluency: Preliminary Tests of a Perceptual Fluency/Attributional Model of the Mere Exposure Effect.'' *Social Cognition,* 12(2):103–128, 1994.

Dated: September 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20623 Filed 9–22–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–E–2364 and FDA–2020–E–2365]

Determination of Regulatory Review Period for Purposes of Patent Extension; NURTEC ODT

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 NURTEC ODT 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 human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 22, 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 March 22, 2023. 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. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 22, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Nos. FDA–2020–E–2364 and FDA–2020–E–2365 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; NURTEC ODT.'' 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 § 10.20 (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 numbers, 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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.