Medicare Beneficiary Database (MBD) (09–70–0536), from the National Claims History File (NCH) (09–70–0558), and from ACOs that provide the information as required to perform the statutory functions of beneficiary assignment, implementation of quality and other reporting requirements, and determination of shared savings.

EXEMPTIONS CLAIMED FOR THIS SYSTEM:

None.

Dated: September 14, 2011.

Michelle Snyder,

Deputy Chief Operating Officer, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–23959 Filed 9–15–11; 11:15 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions

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.

DATES: Fax written comments on the collection of information by October 19, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–New and title ''Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.Vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions—(OMB Control Number 0910–New)

Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) requires advertisements for prescription drugs to include, among other things, ''such information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations.'' Under this authority, FDA has issued regulations to require most prescription drug advertisements to provide a ''true statement of information in brief summary relating to side effects, contraindications, and effectiveness.'' (*§ 202.1(e) (1) (*21 CFR 202.1(e)(1)). To satisfy this requirement, an advertisement that makes claims about a prescription drug must also include a ''fair balance'' of information about the benefits and risks of the advertised product, in terms of both content and presentation (§ 202.1(e)(5)(ii)). In part, *§ 202.1(e)(6)(i) states that* [a]n advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, or otherwise violative of section 502(n) of the act, among other reasons, if it [c]ontains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in *§ 202.1 ''patients'' means humans and in the case of veterinary drugs, other animals)* safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii)(*b*) and (e)(4)(ii)(*c*) of *§ 202.1)* whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

FDA's current regulations provide a limited exception to the requirement in § 202.1(e)(1), of presenting a true statement of information in brief summary, for ''reminder advertisements'' (''reminder ads'')—advertisements that draw attention to the name of the product but do not make representations about the product's indication(s) or dosage recommendations (§ 202.1(e)(2)(i)). (Certain drugs are not permitted to qualify for the reminder advertisement exemption.) To meet the terms of this exemption, reminders ads must in general be limited to the proprietary and established name of the product and the established name of each active ingredient in the drug product. Reminder ads may also (optionally) contain information about the product's quantitative ingredients, dosage form, quantity, price, and manufacturer, as well as other written, printed, or graphic matter containing no representation or suggestion relating to the product. Further, reminder ads that are intended to provide consumers with information concerning the price charged for a prescription drug product need not meet the terms of § 202.1(e)(2)(i) in order to be exempt from § 202.1(e)(1) if they meet all of the conditions in *§ 200.200 (*21 CFR 200.200). That regulation, in turn, applies to prescription drug reminders ads that are intended solely to provide consumers with information concerning the price charged for a prescription for a particular drug product, and the reminder ad contains no representation or suggestion concerning the drug product's safety, effectiveness, or indications for use (§ 200.200(a)(1) and (b)).

A topic of ongoing interest for consumer product manufacturers and retailers is the use of consumer-oriented sales promotions such as free trial offers, discounts, money-back guarantees, and rebates. Such promotions are widely used in many product categories, including prescription drugs.

Prior research has demonstrated that the type of promotion offered can affect how consumers respond to the promotion (Refs. 1, 2, and 3). Price incentives [1] may act as cues about product quality. For example, a price incentive may not only act as an economic incentive to buy the product, it may also artificially enhance consumers' perceptions of the product's quality (Ref. 4). In the case that

[1] In this document, we use the terms ''price incentive'' and ''coupon'' interchangeably to refer to the types of promotional offers to be addressed in our study.

consumers can readily test the performance of some products (termed ''experience'' goods; Ref. 5), this misperception is quickly corrected through the consumer's use of the product. In situations where little information about the product is available or when consumers are unmotivated to seek further information, consumers may use price as a heuristic cue to ascertain the quality of a product. Rao (2005; Ref. 6) has referred to the use of price as a cue to quality as the ''price-quality heuristic,'' where heuristics are conceptualized as mental shortcuts that minimize cognitive effort to process information and are used when individuals are unable or unwilling to engage in more analytical processing of information (Ref. 7). For example, if length of warranty is strongly believed to be a good predictor of quality, then consumers may perceive a product as higher quality when a long warranty is present than when one is not present (Ref. 8). Thus, price incentives may have the potential to act as an ''inference rule'' (or heuristic; Refs. 7 and 9) and, when present, they may preempt consumers from thinking carefully about the product information contained in the advertisement (*i.e.,* fully elaborating on the information). This could result in either favorable or unfavorable beliefs about the product (Refs. 10 and 11). If a price incentive offer acts as a mental heuristic in such a way as to result in an unbalanced or misleading impression of the product's safety or efficacy, however, this would raise concerns for FDA.

Consumers vary in their reactions to price incentive promotions, and researchers and economists have proposed a number of explanations for why some consumers are sensitive to these tactics. Two such traits are ''price consciousness'' and ''belief in the price-quality relationship.'' Price consciousness is defined as the degree to which the consumer focuses exclusively on paying low prices. Belief in the price-quality relationship is defined as the degree to which one believes a higher price indicates superior quality (Ref. 12). A broader trait of ''value consciousness'' has also been used. This trait involves assumptions about the construct of perceived value and its relationship (a ratio) with the constructs of perceived quality and perceived price.

While price incentive promotions have been extensively studied in the context of package goods, information on their effects in direct-to-consumer (DTC) prescription drug ads is limited. One relevant study (Ref. 13) found that a free-trial offer in a DTC ad for a high cholesterol drug resulted in more favorable perceptions of the product and the ad (both rated as good/bad, favorable/unfavorable, and pleasant/unpleasant), and greater intentions to ask about the product. No differences were found in terms of perceived product risk. However, the study did not measure perceptions of product risk and benefit separately, or comprehension of risk and benefit information. Additionally, no attempt was made to control for factors that may predispose individuals toward coupon use nor was the study conducted with the target population (high cholesterol sufferers). We propose to expand on this initial study by measuring perceived product risk and benefit separately, measuring risk and benefit comprehension, investigating a variety of price incentive offers, recruiting a wider range of the target audience from malls and online, and by measuring traits that may predispose individuals to be susceptible to coupon influence.

The current study will examine what effect, if any, the presence of promotional offers in DTC prescription drug ads have on the following: (1) Consumers' perceptions of product risks and benefits, (2) recall of product risks and benefits, and (3) strongly held beliefs that may act as potential moderators.

Design Overview: Study 1: This study will examine types of promotional offers (for example, free trial offer; money off cost; money back guarantee; buy one, get one free; and no offer) in three types of drug advertisements (prescription drug full product, over-the-counter (OTC), and prescription drug reminder). The fictitious test product will treat insomnia and will be modeled on an actual drug used to treat this condition. Participants will be consumers who have insomnia or who self-identify as having met the diagnostic criteria for insomnia. Prescription drug full product advertisements contain information about both benefits and risks, OTC drug advertisements contain benefit information but not risk information, and prescription drug reminder advertisements do not contain either benefit or risk information.

Study 1 will be administered in two modes, online and mall-intercept, in order to assess the effects of mode on study results. Table 1 of this document illustrates the design; the specific promotional offers examined will be determined through pretesting. Offers that demonstrate the most effect on perceptions of product efficacy and risk will be selected for the main study.

Study 1 is experimental in method: participants will be randomly assigned to read one ad version. After reading the ad, participants will answer a series of questions about the drug. We will test how the offer type affects their recall of the benefit and risk information, their perceptions of the benefits and risks of the drug, their perceptions of the incentive, and their behavioral intention to look for more information about the product and try the product. We will also test how mode of administration (online versus mall intercept) affects these variables.

TABLE 1—STUDY 1 DESIGN, MODE 1 (ONLINE, INTERNET PANEL)

Promotional offer (examples)	Type of advertisement		
	Efficacy and risk (prescription full)	Efficacy only (OTC)	None (prescription reminder)
Free trial offer	Online	Online	Online
Buy one, get one free	Online	Online	Online
Money off cost	Online	Online	Online
Money back guarantee	Online	Online	Online
Control: No offer	Online	Online	Online

TABLE 2—STUDY 1 DESIGN, MODE 2 (MALL INTERCEPT)

Promotional offer (examples)	Type of advertisement		
	Efficacy and risk (prescription full)	Efficacy only (OTC)	None (prescription reminder)
Free trial offer	Mall	Mall	Mall
Buy one, get one free	Mall	Mall	Mall
Money off cost	Mall	Mall	Mall
Money back guarantee	Mall	Mall	Mall
Control: No offer	Mall	Mall	Mall

Study 2: We propose to replicate the online mode from Study 1 in a second medical condition, high blood pressure.

TABLE 3—STUDY 2 DESIGN (ONLINE, INTERNET PANEL)

Promotional offer (examples)	Type of advertisement		
	Efficacy and risk (prescription full)	Efficacy only (OTC)	None (prescription reminder)
Free trial offer	Online	Online	Online
Buy one, get one free	Online	Online	Online
Money off cost	Online	Online	Online
Money back guarantee	Online	Online	Online
Control: No offer	Online	Online	Online

The test product in Study 2 will be for the treatment of high blood pressure. Participants will be consumers who have been told by a health care professional that they have high blood pressure. As with Study 1, this study is experimental in method: participants will be randomly assigned to read one ad version. After reading the ad, participants will answer a series of questions about the drug. We will test how the offer type affects perceived efficacy, perceived risk, behavioral intention, and recall of the benefit and risk information.

Data will be collected using an Internet protocol (Studies 1 and 2) and mall intercept (Study 1). Consumers who have insomnia or self-identify as meeting the criteria for insomnia will be recruited for Study 1 and consumers who have been told by a health care professional that they have high blood pressure will be recruited for Study 2. Because the task presumes basic reading abilities, all selected participants must speak and read English fluently. Participants must be 18 years or older. We will use analysis of variance and regressions to test hypotheses. Interviews are expected to last no more than 20 minutes. A total of 5,850 participants will be involved in the studies. This will be a one-time (rather than annual) collection of information.

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the **Federal Register** of September 22, 2010 (75 FR 57798) Docket No FDA–2010–N–0465). FDA received five comments. In the following section, we outline the observations and suggestions raised in the comments and provide our responses.

Two comments wrote in support of the study. We thank those who commented for their support of this research.

(Comment 1) One comment spoke against FDA conducting the research, saying (in part), ''[T]his survey is so unnecessary and such a waste of tax dollars * * * [W]e all know already how consumers take this information * * * [Y]ou can see from teh (sic) way the ads are presented what the big money big pharma con men are up to.''

(Response) We thank the citizen that took the time to comment on this study. The purpose of this study is to examine the potential impact on perceptions of product safety and efficacy of price incentives included in the body of a prescription drug advertisement. We disagree that the field has definitively answered the question of how consumers will ''take this information.'' As described in the background section of the study in Ref. 13 (Bhutada), one study that examined the impact of a price incentive in a prescription drug print advertisement found that consumers who saw an ad with a price incentive had favorable perceptions of the product and the ad, perceptions of the product and greater intentions to ask about the product. No differences were found in terms of perceived product risk. However, the study did not measure perceptions of product risk and benefit separately, or comprehension of risk and benefit information. In addition, we note that the findings of other academic studies in this field point in two different directions; research shows the presence of price incentives can foster beliefs about product quality or diminish beliefs about product quality. Therefore, the lack of information about the potential influence of price incentive offers on risk and benefit comprehension and the conflicting findings in the current literature make this is an opportune area in which to conduct an empirical study.

Two comments included multiple points about the study justification and design. We thank those who provided the comments for taking the time to provide detailed comments on our study and respond to their points in the paragraphs that follow.

(Comment 2) This comment suggested that the proposed study is not necessary for the proper performance of FDA's functions because no evidence of a serious or widespread problem with price incentives has been identified.

(Response) FDA disagrees with this assertion. While no ''serious or widespread problem'' has been previously identified, the Agency has observed increasing use of a variety of price incentive promotional offers in DTC print advertisements for

prescription drugs. The proposed study is intended to help the Agency better understand what effect, if any, these price incentive promotions have on consumer perceptions of risk and benefit information about the advertised prescription drugs. Improving FDA's understanding of these effects will assist the Agency in proactively meeting its responsibility to implement the FD&C Act. As already noted, both the FD&C Act and existing regulations issued to implement it are concerned with ensuring that prescription drug advertisements, including DTC print ads, provide appropriate risk and benefit information and are not otherwise misleading. (See, *e.g.,* 21 U.S.C. 352(n) and 321(n); 202.1(e);) The study will provide information to help the Agency assess how these mandates can be met where price incentives are employed, and is therefore ''necessary for the proper performance of FDA's functions * * *'' (44 U.S.C. 3508).

(Comment 3) This comment suggested that the inclusion of a truthful price incentive in an otherwise compliant DTC advertisement cannot render the advertisement false, misleading or lacking fair balance under the FD&C Act regardless of the psychological theories implicated. The comment further asserted that the inclusion of a truthful price incentive into an otherwise compliant DTC ad cannot serve as the basis for FDA to initiate regulatory action against the ad under the FD&C Act.

(Response) FDA believes that if the inclusion of a ''truthful'' price incentive in promotional material results in an unbalanced net impression of the drug product, that this would create a misleading impression of risk and benefit. As explained in FDA's draft guidance for industry entitled ''Presenting Risk Information in Prescription Drug and Medical Device Promotion,'' it is important to emphasize that when FDA evaluates the risk communication in a promotional piece, FDA looks not just at specific risk-related statements, but at the net impression—*i.e.,* the message communicated by all elements of the piece as a whole. The purpose of the evaluation is to determine whether the piece as a whole conveys an accurate and non-misleading impression of the benefits and risks of the promoted product. Manufacturers should therefore focus not just on individual claims or presentations, but on the promotional piece as a whole. A promotional communication that conveys a deceptive net impression of the product could be misleading, even if specific individual claims or presentations are not misleading (Ref. 14).

Thus, even if a price incentive included in an advertisement is in fact ''truthful,'' the net impression of the promotional piece as a whole can be unbalanced or misleading, which may in turn violate existing regulations. FDA proposes this study to help determine whether or not including a price incentive in a DTC print advertisement for a prescription drug can result in an unbalanced or otherwise misleading net impression of the drug product.

(Comment 4) This comment stated that the study may provide interesting information about the effect of price incentives on consumer attitudes toward a brand and useful information on optimal advertising practices, but it cannot provide information relevant to the statutory and regulatory requirements applicable to DTC advertising.

(Response) FDA disagrees that the study cannot provide information relevant to the statutory and regulatory requirements applicable to DTC advertising. As noted previously, this study will examine issues that are well within FDA's regulatory authority—whether the inclusion of price incentives in prescription drug ads impacts a consumer's understanding of the risk and benefit information of the drug. In particular, we are interested to learn whether the inclusion of price incentives can interfere with the fair balance of information and cause a misleading net impression. Knowing whether or not misleading impressions result is a prerequisite to considering how any such misleading effects should be addressed.

(Comment 5) One comment contends that the citation to § 202.1(e)(6)(i) included in the 60-day notice (75 FR 57798) is inaccurately truncated, and further asserts that the only indirect claims and representations subject to this regulation are those made through use of literature, quotations, or other references. The comment argues that because price incentives do not involve the use of published or unpublished literature, quotations or other references, this provision does not provide a legal basis for the proposed study or for the Agency to regulate the heuristic effects (if any) of price incentives.

(Response) In response to the comment's concern that FDA inaccurately truncated the regulation, and to avoid misunderstanding, FDA has included a longer excerpt of § 202.1(e)(6) in this notice than was included in the prior notice. However, FDA disagrees with the comment's conclusion about the justification for the proposed study.

As an initial matter, as noted, FDA has authority under section 502(n) of the FD&C Act to specify by regulation how to present the brief summary of risk and benefit information required in prescription drug advertisements. This authority, together with FDA's authority to conduct research relating to drugs (21 U.S.C. 393(d)(2)(c)), amply supports the proposed study. FDA need not establish that it would bring enforcement actions under § 202.1(e)(6)(i) or any other specific provisions of the present regulations in order to justify conducting a study that is intended to provide a better empirical understanding of the impact, if any, on risk and benefit information communication where price incentives are included in DTC print advertisements for prescription drugs. The results of this study will help to inform FDA's review of, and regulatory policies for, prescription drug advertising subject to section 502(n) of the FD&C Act.

Turning specifically to § 202.1(e)(6), we disagree with the comment's construction of that regulation. As indicated in the prefatory text of § 202.1(e)(6), the specifics that follow are ''among other reasons'' that an advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, indicating that these are examples and not an exclusive list as the comment assumes. In the same vein, § 202.1(e)(6)(i) states that an advertisement may not contain: A representation or suggestion, not approved or permitted for use in the labeling, that a drug is better, more effective, useful in a broader range of conditions or patients (as used in *§ 202.1 ''patients'' means humans and in the case of veterinary drugs, other animals*) safer, has fewer, or less incidence of, or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience (as described in paragraphs (e)(4)(ii)(*b*) and (e)(4)(ii)(*c*) of *§ 202.1*) whether or not such representations are made by comparison with other drugs or treatments, and whether or not such a representation or suggestion is made directly or through use of published or unpublished literature, quotations, or other references.

This phrasing prohibits ''a representation or suggestion, not approved or permitted for use in the labeling'' even if the representation or suggestion is not made via the means given as examples in the regulation. Thus, FDA has consistently, and

appropriately, examined both direct and indirect representations and suggestions when examining the net impression presented in a prescription drug advertisement.

(Comment 6) One comment asserts that the citation to § 202.1(e)(6)(xviii) is inappropriate because this regulation concerns only the presentation of heading and subheadings and FDA is studying the mere fact that a price incentive has been made, not the way in which headline, subheadline, or pictorial or other graphic matter are used to communicate that price incentive.

(Response) FDA does not need to rely on § 202.1(e)(6)(xviii) to justify the proposed study therefore we have removed the reference to this regulation.

(Comment 7) One comment contends that the scientific research identified does not provide justification for conducting the study nor does it provide support for the proposition that promotional offers have the capacity to act as a cue or a heuristic with respect to prescription drugs.

(Response) We acknowledge that there is little research on the impact of price incentive offers in prescription drug advertising. The paucity of existing research is a primary motivation for the proposed research. The question of whether or not a price incentive offer can affect perceptions of and recall of prescription drug efficacy and risk is an empirical one and will be tested in the proposed study.

(Comment 8) One comment directly questioned the need to conduct this study in light of the results found by Bhutada *et al.* (Ref. 13; 2009). Specifically, the comment asserts that the study found no effect of a price incentive on consumer comprehension of risks or benefits of the prescription drug.

(Response) As noted previously, the Bhutada *et al.* study did not measure perceptions of product risk and benefit separately. Perceptions of product risk and benefit were measured on a scale with risk at one end and benefits at the other, so it was not possible to assess the effects of the price incentive on risks and benefits separately. Further, comprehension of risk and benefit information was not measured at all, so it is impossible to determine from this study if there was an effect on comprehension. The current proposed study will extend this initial study by measuring perceived product risk and benefit separately, measuring risk and benefit comprehension, investigating a variety of promotional offers, recruiting a wider range of the target audience from malls and online, and by measuring traits that may predispose individuals to be susceptible to influence in their perceptions of risk or benefit by a price incentive.

(Comment 9) One comment asserts that heuristic effects are not claims, either expressed or implied, and since reminder ads do not include any safety or effectiveness information, there is no basis even to argue that they may preempt consumers from thinking carefully about the product information contained in the reminder ad.

(Response) It is an empirical question whether price incentives operate as a heuristic cue and further, whether those cues impact perceptions of product characteristics (in this case, the product's efficacy and risk). As the literature on heuristic judgment demonstrates, individuals are frequently faced with situations in which they are required to make judgments using incomplete information and are able to do so (Refs. 15 and 16). Therefore, it is reasonable to test whether an incentive can influence this judgment in the context of both a full-product and a reminder DTC prescription drug advertisement.

(Comment 10) One comment asserts that the regulation explicitly permits companies to include information about price within reminder ads. The comment argues that because price incentives pertain to price, this regulation provides no legal basis for the proposed study or for the Agency to regulate price incentives contained in reminder ads.

(Response) FDA acknowledges that current regulations permit reminder ads to include price information under defined conditions, while remaining exempt from the requirement for a ''true statement of information in brief summary.'' FDA does not intend to use the results of this study to regulate drug prices. In this study, FDA is only seeking to assess the effects, if any, of the presence of various offers in DTC advertisements on consumers' perceptions of product risks and benefits. As stated previously, we will use ''reminder ads'' in this study to understand the effect of offers on consumer perceptions of safety and efficacy. Reminder ads present a useful tool in determining this effect as broad safety and efficacy information is not otherwise provided in such advertisements. Results of this preliminary study will help FDA in its assessment of drug ads and in broader assessment of its regulatory policy for effectuating section 502(n) of the FD&C Act and other legal authorities governing drug promotion.

(Comment 11) One comment said that FDA has not established standards by which to judge the results of the study. This comment asserted that even if consumers have a more positive view of the safety or effectiveness of a product with a price incentive compared to one that does not, this does not automatically deem the ad false, lacking in fair balance, or otherwise misleading.

(Response) To judge the results of our study, we take our cue from the related field of research conducted on potentially misleading claims and employed frequently by the Federal Trade Commission in their investigations of advertising claims (Ref. 17). In this research, an ad with the content at issue removed serves as an appropriate experimental control. Based on this precedent, an ad without a price incentive is an appropriate control in this study.

(Comment 12) One comment stated that unless FDA can establish that differences in perceptions of safety or efficacy are not due to differences in price and/or the size of the price incentive, any restrictions or requirements on price incentives will require FDA to regulate prescription drug pricing.

(Response) As previously acknowledged, the FD&C Act does not provide FDA with authority to regulate prescription drug pricing and that is not the purpose or intended outcome of this study. The purpose of the currently proposed study is to investigate how different purchase incentives, including ones that may affect the actual price of the product, may operate in the context of a DTC ad. If we find that some types or all types of offers do influence viewers' comprehension and perceptions of safety or effectiveness, then, as suggested by this comment, the next logical step may be to conduct further study to disentangle the effects of the presence of the offer itself and the magnitude of the price incentives. In one research study we do not have the ability to examine all variables of interest, however, and we believe the variables we have chosen for the proposed study are reasonable.

(Comment 13) One comment asserted that by equating cues and inference rules with product claims, FDA risks imposing restrictions on DTC advertising based on potential deception rather than actual deception, which the comment argues is fraught with risk under the First Amendment. This comment cites the following from *Washington Legal Foundation* v. *Henney* (56 F. Supp. 2d 81, 85 (D.D.C. 1999)), ''FDA may not restrict speech based on its perception that the speech

could, may, or might mislead.'' The comment urges FDA to carefully consider First Amendment issues before proceeding with the study.

(Response) We have carefully considered First Amendment issues in designing this study. The *Washington Legal Foundation* v. *Henney* case cited by the comment notes that ''the government must demonstrate that the restricted speech, by nature, is more likely to mislead than to inform'' (*Id.* at 85). It is the goal of the proposed study to investigate whether a price incentive may or may not be ''more likely to mislead than to inform.''] Our participants will view a fictitious but realistic DTC print ad and answer questions about that ad. From their answers we will be able to determine their responses to the information in the ad. Thus, we will measure whether the ad is actually misleading and not potentially misleading. The experimental control afforded by participants' random assignment to different experimental conditions ensures that we will be able to pinpoint the source of any differences in responses to ad variations by comparing responses of participants who see the variables of interest (in this case, the offer) versus those who do not.

(Comment 14) One comment stated that the proposed study appears to be designed more to assess the effect of coupons on brand attitudes and consumer impressions and does not appear to be tailored to assess the effect of price incentives on statutory and regulatory requirements. In other words, the comment argues that FDA has no regulatory authority to manage or regulate consumer attitudes or impressions toward a brand.

(Response) As noted previously, the study is designed to determine whether price incentive offers embedded in prescription drug ads can result in a misleading net impression of risk and benefit, which may in turn violate existing regulations under the FD&C Act. We will measure the effect of the offer on consumer's understanding of the product's efficacy and safety and the net impression of the product created by a promotional piece in regards to that piece alone, which will inform our review of DTC prescription drug advertising generally. FDA does not intend to regulate or manage consumer attitudes or impressions towards a particular brand.

(Comment 15) One comment questioned the utility of including the reminder and OTC test arms in the study as these advertisements do not include both safety and effectiveness information.

(Response) As stated previously, individuals are frequently faced with situations in which they are required and able to make judgments using incomplete information. As detailed previously, the inclusion of a prescription reminder ad and an OTC ad provides experimental control. We will compare perceptions of the product attributes among participants who see: (1) Full risk and efficacy information (full ad), (2) only efficacy information (OTC ad), and (3) neither risk nor efficacy information (prescription reminder ad). The question of whether an incentive can influence this judgment in the context of a DTC prescription drug advertisement is the empirical question we are addressing in the proposed study.

(Comment 16) Two comments requested FDA provide more information on the study population and study design including the primary research questions, stimuli, endpoints, and action standards.

(Response) The proposed questionnaire has been and continues to be available upon request. We refer to pages 57800 and 57801 of the 60-day notice (75 FR 57798) where the study design was described. We have described the primary research questions in more detail in this 30-day notice. Specific hypotheses and the analysis plan are included in this document.

(Comment 17) One comment requested that FDA specify the types of advertisements to be used in the study (*i.e.,* spread, gatefold, ⅓ page ad). Another comment requested that FDA engage the services of an advertising agency that specializes in the development of DTC print advertisements. Further, the comment asserted that the location of the promotional offer may have an impact on consumer perceptions of product risks and benefits and requested FDA define the location of the offer and clarify if it will be varied in the test ads.

(Response) The full product DTC ad will be two pages, including a brief summary. The OTC ad and reminder ad will each be one page. We have contracted with an organization that produces realistic ads and stimuli to ensure that we will show respondents realistic materials. The location of the promotional offer will be standardized as much as possible across all test conditions and will be incorporated in such a way as to not obscure the description of either the risks or benefits in the full product ad.

(Comment 18) One comment requested FDA identify and study more general disclosures that are not directly related to safety or effectiveness info, such as ''consult with a physician to discuss whether this drug is right for you.''

(Response) We appreciate the comment about widening the scope of the disclosures to be studied. Based upon the suggestion of our peer reviewers, we have changed the focus of the second study to examine a second medical condition and will not be investigating disclosures as part of this initial study. We encourage other interested entities to engage in research on disclosures.

(Comment 19) One comment requested that the study population be limited to individuals who have been diagnosed with the medical condition of interest and exclude those merely 'at risk' of developing the condition because those who do not have the medical condition may be much less attentive to the information in the ad and thus skew the study results. In another paragraph, the same comment questioned the need to conduct the proposed study in the target population since doing so would not yield different results from Bhutada *et al.* (2009) who did not use diagnosed individuals.

(Response) As these two suggestions are contradictory, we offer our reasoning behind selecting participants in Study 1 who are either diagnosed or fit the criteria for diagnosis of insomnia (formerly referred to as ''at risk''). One purpose of a purchase incentive is to encourage new users to try a product (Ref. 18). Similarly, the first of the Pharmaceutical Research and Manufacturers of America's (PhRMA) guiding principles on direct to consumer advertising (Ref. 19) states that ''* * * DTC advertising of prescription medicines can benefit the public health by * * * motivating patients to contact their physicians and engage in a dialogue about health concerns * * *'' Inclusion of an incentive might encourage a consumer who recognizes the symptoms described in the advertisement to discuss the condition with a doctor or other health care professional. Thus, we conclude that both diagnosed patients and those individuals who self-report meeting the diagnostic criteria for the advertised medical condition but have not yet been diagnosed are a valid sample for Study 1. We are limiting our Study 2 sample to individuals who have been diagnosed with high blood pressure by a health care professional.

(Comment 20) One comment requested that demographic information such as age, education, income, ethnicity, race, a baseline assessment of health literacy, and whether the

consumer is currently being treated with a prescription drug for the condition being studied be included in the information collection.

(Response) Demographic and health literacy information will be collected.

(Comment 21) One comment requested that FDA use prudence when broadly interpreting the results from this study and developing subsequent guidance based on these study results, and requested that the results of the study not be applied beyond print ads or, alternatively, to expand the study to include Internet promotion.

(Response) At this time we cannot expand the study to encompass Internet promotion. We concur that there are media-specific factors that influence information processing between static (*e.g.,* print) and dynamic (*e.g.,* video) platforms, and will note that our study was conducted with print ads in our interpretation of the results. However, we contend that the cognitive processes used in understanding and interpreting incentive information are likely to apply across promotional platforms.

(Comment 22) Two comments mentioned that the study does not assess how consumer perceptions of product risks and benefits are translated into a discussion with their health care provider. One comment stated that because these products can only be purchased after a discussion with a health care provider, the study be redesigned so that consumer perceptions are measured after a discussion with a health care provider.

(Response) We concur that this study does not address behaviors, such as how ad perceptions are translated into a discussion with a health care provider. As noted previously, one purpose of DTC advertising is to motivate consumers to engage in a discussion with their health care provider about health concerns. Another purpose, supported by research findings (Refs. 20 and 21), is to increase awareness of available treatments. DTC advertising does not exist solely in the confines of a doctor's office; rather, DTC advertising targets consumers outside of a doctor's office, with the goal of prompting consumers to ask their physicians about the product. In deciding whether or not to discuss a particular product with their health care provider, consumers presumably are engaging in some sort of judgment about the product being promoted. Therefore, clear communication of risks and benefits is needed for consumers before a consultation with a physician, and it is valid to measure these impressions.

(Comment 23) One commenter requested that FDA provide clarity on the timing of this study vis-a-vis other FDA DTC studies and make available the results of previous DTC studies on the Division of Drug Marketing Advertising and Communications (DDMAC) Research Web page.

(Response) The timing of this study is not dependent on other research currently underway. We have taken steps to publish reports from our previous research on the DDMAC Web page (see *http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090276.htm*). When the current project is concluded, we will report on the study.

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

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	8,500	1	8,500	.03 (2 minutes)	283
Pretests	1,000	1	1,000	.33 (20 minutes)	333
Study 1: Online	1,950	1	1,950	.33 (20 minutes)	650
Study 1: Mall intercept	1,950	1	1,950	.33 (20 minutes)	650
Study 2	1,950	1	1,950	.33 (20 minutes)	650
Total	15,350				2,566

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

II. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

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Dated: September 12, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–23926 Filed 9–16–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0620]

Draft Guidance for Industry on Self-Selection Studies for Nonprescription Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Self-Selection Studies for Nonprescription Drug Products.'' The draft guidance is intended to provide recommendations to industry on the design of self-selection studies for nonprescription drug products. Self-selection studies are conducted to ensure that consumers are able to make the correct decision to use, or not use, a nonprescription drug product based on their personal medical situation.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 18, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lesley-Anne Furlong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5420, Silver Spring, MD 20993–0002, 301–796–2080.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Self-Selection Studies for Nonprescription Drug Products.'' This draft guidance is intended to provide recommendations to industry involved in the development of self-selection studies for nonprescription drug products. The draft guidance discusses general concepts to be considered in the design and conduct of a self-selection study. The draft guidance also incorporates advice obtained from the Nonprescription Drugs Advisory Committee at a meeting held on September 25, 2006, which considered issues related to the analysis and interpretation of consumer studies conducted to support the marketing of nonprescription drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on self-selection studies for nonprescription drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 13, 2011.

Leslie Kux,

Acting Assistant Commission for Policy.

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