FEDERAL MARITIME COMMISSION

Rescission of Order of Revocation

Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409 and 46 CFR Part 515). Notice is hereby given that the Rescission of Order of Revocation Order is rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409 and 46 CFR Part 515). Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409 and 46 CFR Part 515).

FEDERAL MARITIME COMMISSION

Ocean Transportation Intermediary License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission an application for a license as a Non-Vessel Operating Common Carrier (NVO) and/or Ocean Freight Forwarder (OFF)—Ocean Transportation Intermediary (OTI) pursuant to section 19 of the Shipping Act of 1984 as amended (46 U.S.C. Chapter 409 and 46 CFR Part 515). Notice is hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) license.

Interested persons may contact the Office of Transportation Intermediaries, Federal Maritime Commission, Washington, DC 20573.

For Further Information Contact:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852. Elizabeth.Berbakos@fda.hhs.gov.
Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Experimental Study: Effect of Promotional Offers in Direct-to-Consumer (DTC) Prescription Drug Promotion Print Advertisements on Consumer Product Perceptions—New**

**Regulatory 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 903(d)(2)(C) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to drug product, and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.**

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Experimental Study: Effect of Promotional Offers in Direct-to-Consumer (DTC) Prescription Drug Promotion Print Advertisements on Consumer Product Perceptions—New**

Regulatory 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 903(d)(2)(C) of the 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.

FDA regulations require that an advertisement that makes claims about a prescription drug include a “fair balance” of information about the benefits and risks of the advertised product, in terms of both content and presentation (21 CFR 202.1(e)(5)(ii)). In part, “[a]n advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading” if it “contains a representation or suggestion that is 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” if “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” 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 (21 CFR 202.1(e)(6)(i)). Further, the regulations state that an advertisement may be misleading if it “[u]ses headline, subheadline, or pictorial or other graphic matter in a way that is misleading” (21 CFR 202.1(e)(6)(xviii)).

Advertisements that draw attention to the name of the product but do not make representations about the product’s indication(s) or dosage recommendations are called reminder advertisements. As a general matter, reminder ads may mention the proprietary and established name of the product and (optionally) contain information about the product’s indications, dosage form, quantity, price, and manufacturer (21 CFR 202.1(e)(2)(ii)). Other written, printed, or graphic information is not prohibited in reminder ads as long as that information does not make a representation or suggestion relating to the product beyond those permitted.

**Rationale.** 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, rebates, and sweepstakes. Coupon 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. For example, a price incentive may not only act as an economic incentive to buy the product, but may also artificially enhance consumers’ perceptions of the product’s quality. In cases where consumers can


9 See, for example, France, K.R. and P.F. Bone, “Policy Makers’ Paradigms and Evidence From

Continued
effectiveness of disclosures, particularly those that take the form of a disclaimer.10,11 However, there may be other ways to add information that is effective in changing processing. One possibility is including specific information about a prescription drug product’s efficacy from labeling. This information may act as a signal with regard to the quality of the information (good or bad). By extension, this signal may affect the use of processing heuristics. Depending on the type of signal and the extent to which consumers process the signal, full elaboration of the product information may be enhanced (as use of heuristics decreases).

Consumers vary in their reactions to promotions such as coupons 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.10 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 promotions have been extensively studied in the context of package goods, information on their effects in DTC prescription drug ads is limited. One relevant study 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), 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. 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). The current study will expand on this initial study by investigating a variety of promotional offers, recruiting a wider range of the target audience from malls and online, measuring traits that may predispose individuals to be susceptible to coupon influence, and by exploring the effects of disclosures on the processing of product information.

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) comprehension of product risks and benefits, and (3) strongly held beliefs that may act as potential moderators. The study will also explore ways in which additional contextual information can be used to enhance processing of the product information in the advertisement.

**Design Overview**

This study will examine type of promotional offer (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 reminder ad, prescription drug full product ad, and over-the-counter (OTC) drug ad) in a medium prevalence medical condition (defined as 10 percent prevalence in the adult U.S. population). The study will be administered in two modes, online and mall-intercept, in order to assess the effects of mode on study results. The following table illustrates the design; the specific promotional offers examined will be determined through pretesting. This study is experimental in method: participants will be randomly assigned to condition.

**Main Study Design**

<table>
<thead>
<tr>
<th>Promotional Offer (examples)</th>
<th>Full Product</th>
<th>Reminder</th>
<th>OTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Free trial offer</td>
<td>Online</td>
<td>Online</td>
<td>Online</td>
</tr>
<tr>
<td>Buy one, get one free</td>
<td>Online</td>
<td>Online</td>
<td>Online</td>
</tr>
<tr>
<td>Money off cost</td>
<td>Online</td>
<td>Online</td>
<td>Online</td>
</tr>
<tr>
<td>Money back guarantee</td>
<td>Online</td>
<td>Online</td>
<td>Online</td>
</tr>
<tr>
<td>Control: No offer</td>
<td>Online</td>
<td>Online</td>
<td>Online</td>
</tr>
</tbody>
</table>

We also propose to conduct a supplementary exploratory study to examine the influence of additional information as a form of context. The supplementary study will examine the effect of some forms of qualifying context in a full product prescription drug ad. This supplementary study will examine type of context (for example, additional information about product risks, additional information about product benefits, additional information about product savings, etc.) on the effects of the product information presented in the ad. We will use a 2 (contextual information: presence vs. absence) x 2 (contextual information: high vs. low) between-subjects design. The contextual information will be manipulated in the ad itself, with participants reading the ad and then completing a series of post-test measures. The contextual information will be presented in two forms: as a separate paragraph of text or as a graphical representation such as a chart or diagram. By comparing the effects of these two types of contextual information, we can determine which form is most effective at enhancing consumers’ understanding of the product information presented in the ad.
about both risks and benefits, and no additional information) in three different promotional offers (money back guarantee and two others) in a medium prevalence medical condition (defined previously). This supplemental study will be conducted online. One type of offer examined will be money back guarantee; we will choose the other two types of promotional offers based on the results of the main study. The exact wording of the qualifying context to be examined will be determined through pretesting. This study is experimental in method: Participants will be randomly assigned to condition. Supplementary Study Design

<table>
<thead>
<tr>
<th>Type of Context (examples)</th>
<th>Money Back Guarantee</th>
<th>Offer 2</th>
<th>Offer 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional information about risk</td>
<td>To be determined</td>
<td>To be determined</td>
<td></td>
</tr>
<tr>
<td>Additional information about efficacy</td>
<td>To be determined</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional information about efficacy and risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control: No Context</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Interviews are expected to last no more than 20 minutes. A total of 10,000 participants will be involved in the pretesting and two phases of the study. This will be a one time (rather than annual) collection of information.

**Table 1.—Estimated Annual Reporting Burden**

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pretests</td>
<td>1,000</td>
<td>1</td>
<td>1,000</td>
<td>.33</td>
<td>330</td>
</tr>
<tr>
<td>Main study: online</td>
<td>3,750</td>
<td>1</td>
<td>3,750</td>
<td>.33</td>
<td>1,238</td>
</tr>
<tr>
<td>Main study: mall intercept</td>
<td>2,250</td>
<td>1</td>
<td>2,250</td>
<td>.33</td>
<td>743</td>
</tr>
<tr>
<td>Supplementary study</td>
<td>3,000</td>
<td>1</td>
<td>3,000</td>
<td>.33</td>
<td>990</td>
</tr>
<tr>
<td>Total</td>
<td>10,000</td>
<td></td>
<td></td>
<td></td>
<td>3,301</td>
</tr>
</tbody>
</table>

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


Leslie Kux,
Acting Assistant Commissioner for Policy.
[FR Doc. 2010–23632 Filed 9–21–10; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0447]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the information collection in “Medical Devices Third-Party Review under the Food and Drug Administration Modernization Act of 1997.”

DATES: Submit either electronic or written comments on the collection of information by November 22, 2010.

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–5156, Daniel.Gittleson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60–day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an