Address: 2500 NW. 79th Avenue, Suite 200, Miami, FL 33122.

Date Revoked: August 26, 2010.

Reason: Failed to maintain a valid bond.

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2010–23679 Filed 9–21–10; 8:45 am]

BILLING CODE 6730–01–P

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Notice is hereby given that the Order revoking the following license is being rescinded by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. Chapter 409) and the regulations of the Commission pertaining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

License Number: 004063F.

Name: VIP Transport, Inc.

Address: 2703 Wardlow Road, Corona, CA 91720.

Order Published: FR: 9/1/2010 (Volume 75, No. 169, Pg. 53697).

Sandra L. Kusumoto,

Director, Bureau of Certification and Licensing.

[FR Doc. 2010–23675 Filed 9–21–10; 8:45 am]

BILLING CODE 6730–01–P

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 515). Notice is also hereby given of the filing of applications to amend an existing OTI license or the Qualifying Individual (QI) for a license.

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

Allright Shipping, Inc. (NVO & OFF), 1350 Bronx River Avenue, Bronx, NY 10472. *Officer:* Denzil Barker, President, (Qualifying Individual). Application Type: New NVO & OFF License.

Cambria Global Logistics, LLC (OFF), 12140 Quilting Lane, Boca Raton, FL 33428. *Officers:* Panu Virtanen, Managing Member, (Qualifying Individual). Kathleen Virtanen, Managing Member. Application Type: New OFF License.

Glory Express Inc. (NVO), 19825 Hamilton Avenue, Torrance, CA 90502. *Officer:* JinYoung Bae, President/Secretary/CFO, (Qualifying Individual). Application Type: QI Change.

K&K Express, LLC dba K2 Logistics (NVO & OFF), 2980 Commers Drive, #100, Eagan, MN 55121. *Officers:* Wanda L. Dessent, Vice President-International-Houston, (Qualifying Individual). Christiaan Walhof, CEO/President/CFO. Application Type: QI Change.

Overseas Cargo, Inc. (NVO & OFF), 9614 Pondwood Road, Boca Raton, FL 33428. *Officer:* Suramya (A.K.A. Ron) T. Atapattu, President/Secretary/Treasurer/Director, (Qualifying Individual). Application Type: New NVO & OFF License.

Smile Cha dba SMH Global Transport (NVO), 8636 York Circle, La Palma, CA 90623. *Officer:* Smile Cha, Sole Proprietor, (Qualifying Individual). Application Type: New NVO License.

Westwind Shipping and Logistics, Inc. (NVO), 38 West 32nd Street, Suite 1309B, New York, NY 10001. *Officer:* Harry Taurani, President/Secretary/Treasurer/CFO, (Qualifying Individual). Application Type: New NVO License.

World Class Solutions LLC (NVO & OFF), 3901 NW 79th Avenue, Suite 230, Doral, FL 33166. *Officer:* Jorgelina G. Marsaglia, President, (Qualifying Individual). Application Type: New NVO & OFF License.

Dated: September 17, 2010.

Karen V. Gregory,

Secretary.

[FR Doc. 2010–23676 Filed 9–21–10; 8:45 am]

BILLING CODE 6730–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0465]

Agency Information Collection Activities; Proposed Collection; 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 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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Experimental Study: Effect of Promotional Offers in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Product Perceptions. This study is designed to investigate the impact of the presence of coupons offering purchase incentives such as free-trial offers, discounts, and money-back guarantees on consumers' perceptions of product risks and benefits in direct-to-consumer (DTC) print ads.[1] Notice of proposed information collection for this project was previously published in the **Federal Register** of December 15, 2008 (73 FR 76034). This notice is being republished due to significant revisions in the burden and study design.

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: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the

[1] While the Federal Food, Drug and Cosmetic Act (the FD&C Act) provides FDA with authority to regulate prescription drug advertisements that are false or misleading, the FD&C Act does not provide FDA with the authority to regulate the pricing of prescription drugs. Thus, FDA is merely interested in studying the effects, if any, of the presence of various promotional offers in DTC advertisements on consumers' perceptions of product risks and benefits, and recognizes that it does not actually regulate the dollar or other incentive amount of coupons, price incentives, or rebate offers with respect to how they affect the price of prescription drugs or biological products.

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 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 [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* * *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 ingredients, dosage form, quantity, price, and manufacturer (21 CFR 202.1(e)(2)(i)). 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.[2] 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.[3] In cases where consumers can readily test the performance of the products (termed "experience" goods[4]), this misperception is quickly corrected through the consumer's use of the product. However, because prescription drugs are both more complex and riskier than simpler experience products, misperceptions before product use are a serious concern.

Price incentives may mislead consumers because consumers may use the incentives as cues about product quality. 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.[5] Thus, price incentives may have the potential to act as an "inference rule" (or heuristic[6]) 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.[7] If the promotional offer is used as a mental heuristic in such a way as to result in a misleading impression of the product, however, this raises concerns.

It may be possible to encourage more thorough processing of information and reduce reliance on heuristics through the inclusion of additional information designed to qualify and be processed at the same time as the claim in question. For example, disclosures (statements that qualify, limit, or explain a particular claim) are intended to be an information remedy to combat potential deception.[8] Research is mixed on the

[2] See for example, deGroot, I.M., G. Antonides, D. Read, et al., "The Effects of Direct Experience on Consumer Product Evaluation," *Journal of Socio-Economics*, 38(3), 509–519, 2009; DelVecchio, D., D.H. Henard, and T.H. Freling, "The Effect of Sales Promotion on Post-Promotion Brand Preference: A Meta-Analysis," *Journal of Retailing*, 82(3), 203–213, 2006; Mico, C.C. and T.G. Chowdhury, "The Effect of Message's Regulatory Focus and Product Type on Persuasion," *Journal of Marketing Theory and Practice*, 18(2), 181–190, 2010.

[3] LeClerc, F. and J.D.C. Little, "Can Advertising Copy Make FSI Coupons More Effective?," *Journal of Marketing Research*, 34(4), 473–484, 1997.

[4] Wolk, A. and C. Ebling, "Multi-Channel Price Differentiation: An Empirical Investigation of Existence and Causes," *International Journal of Research in Marketing*, 27(2), 142–150, 2010.

[5] Johar, G.V. and C.J. Simmons, "The Use of Concurrent Disclosures to Correct Invalid Inferences," *Journal of Consumer Research*, 26(4), 307, 2000.

[6] Chaiken, S., A. Liberman, and A. Eagly, "Heuristic and Systematic Proocessing Within and Beyond the Persuasion Context," 1989; In J.S. Uleman and J.A. Bargh (Eds.), Unintended Thought (chapter 7, p. 212–252), Guilford Press: New York; Bettman J.R., M.F. Luce, and J.W. Payne, "Constructive Consumer Choice Processes," *Journal of Consumer Research*, 25(3), 187–217, 1998.

[7] Alba, J.W. and H. Marmorstein, "The Effects of Frequency Knowledge on Consumer Decision Making," *Journal of Consumer Research*, 14(1), 14–25, 1987; Inman, J.J., L. McAlister, and W.D. Hoyer, "Promotion Signal: Proxy for a Price Cut?," *Journal of Consumer Research*, 17(1), 74–81, 1990.

[8] FTC (Federal Trade Commission) (1983), Federal Trade Commission policy statement on deception, appended to Cliffdale Associates, Inc., 103 F.T.C. 110 (1984), Available at *http://www.ftc.gov/bcp/policystmt/ad-decept.htm*, Last accessed September 8, 2010; Hoy, M.G and M.O. Lwin, "An International Perspective of Online Disclosure Information: A Comparison of Banner Ad Disclosures from United States, United Kingdom and Singapore Websites," *Journal of Consumer Policy*, 31, 327–347, 2008.

[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.[9] 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[11] 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.[12]

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[13]) 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

	Type of Advertisement					
Promotional Offer (*examples*)	Full Product		Reminder		OTC	
Free trial offer	Online	Mall	Online	Mall	Online	Mall
Buy one, get one free	Online	Mall	Online	Mall	Online	Mall
Money off cost	Online	Mall	Online	Mall	Online	Mall
Money back guarantee	Online	Mall	Online	Mall	Online	Mall
Control: No offer	Online	Mall	Online	Mall	Online	Mall

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

Consumer Interpretations of Dietary Supplement Labels," *Journal of Consumer Affairs*, 39(1), 27–51, 2005; Mason, M.J., D.L. Scammon, and X. Fang, "The Impact of Warnings, Disclaimers and Product Experience on Consumers' Perceptions of Dietary Supplements," *Journal of Consumer Affairs*, 41(1) 74–99, 2007.

[10] Garretson, J.A. and S. Burton, "Highly Coupon and Sale Prone Consumers: Benefits Beyond Price Savings," *Journal of Advertising Research*, 43, 162–172, 2003.

[11] Bhutada, N.S., C.L. Cook, and M. Perri, "Consumer Responses to Coupons in Direct-to-Consumer Advertising of Prescription Drugs," *Health Marketing Quarterly*, 26, 333–346, 2009.

[12] Because FDA does not have the authority to regulate prescription drug pricing we will not examine prescription drug prices.

[13] Prescription drug full product advertisements contain information about both benefits and risks, whereas prescription drug reminder advertisements do not contain this information. OTC drug advertisements contain benefit information but not risk information, thus making it a good choice for an experimental comparison.

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

	Type of Offer		
Type of Context (*examples*)	Money Back Guarantee	Offer 2 To be determined	Offer 3 To be determined
Additional information about risk			
Additional information about efficacy			
Additional information about efficacy and risk			
Control: No Context			

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

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

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

Dated: September 16, 2010.

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