JTI

2012 FEB 16 A 11:37

February 13, 2012

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA–2011–N–0867 (76 Fed. Reg. 77837 (Dec. 14, 2011))

JT International U.S.A., Inc., ("JTI USA"), the U.S. subsidiary of Japan Tobacco International, appreciates the opportunity to comment on the proposed collection of information for the Experimental Study on the Public Display of the List of Harmful and Potentially Harmful Tobacco Constituents ("HPHCs"). We applaud FDA for taking a research-based approach to generate evidence on HPHCs consistent with section 904(d)(1) of the Federal Food, Drug, and Cosmetic Act ("FDCA"). Publication of the HPHC list "in a format that is understandable and not misleading to a lay person" presents unique challenges.

Although JTI USA is supportive of FDA's efforts to assess how consumers understand information about HPHCs, the FDA notice does not provide sufficient detail regarding the design of the proposed consumer research study to allow meaningful comments. JTI USA encourages FDA to provide additional information for public comment as it develops the study, including details of the protocol, screener and questionnaire to be used with study participants. Doing so will promote transparency, provide valuable information to the agency, avoid generation of flawed data, and help assure that HPHC lists are published in an understandable and non-misleading manner.

I. FDA has Welcomed Industry Participation in the Design of Similar Consumer Research Studies.

On several recent occasions, FDA has invited public comment and utilized input from the regulated industry in the design of consumer research studies intended to assist FDA in executing its regulatory responsibilities. On June 16, 2010, FDA published a notice soliciting comments on its Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs, designed to investigate efficacy and effectiveness information of prescription drugs as conveyed to healthcare providers through approved labeling and to consumers through print advertisements.[1] The notice described the

[1] 75 Fed. Reg. 34142 (Jun. 16, 2010).

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purpose of the project, as well as providing detailed information on the proposed study design. FDA received comments from industry expressing support for the research and recommending improvements to the study.[2] The comments included recommendations on the draft study questionnaire provided by FDA. FDA agreed with many of the comments, and incorporated changes in the study in response to the comments. FDA also provided clarification in response to questions.

FDA also recently solicited public comment on the proposed collection of information with respect to two consumer surveys relating to food labeling initiatives: "Experimental Study on Consumer Responses to Whole Grain Labeling Statements on Food Packages"[3] and "Experimental Study on Consumer Responses to Labeling Statements on Food Packages."[4] FDA received several comments from industry that provided recommendations on the draft protocols and questionnaires, which were provided by FDA. These responses are now under consideration by FDA. Industry comments provide first-hand knowledge directly from the professionals whose business it is to know and understand as much about the subject as possible and provide valuable information to assist FDA in refining study protocols, creating more efficacious questionnaires and to best utilize FDA resources.

II. Public Participation Helps to Enhance the Quality, Utility and Clarity of Information Generated in FDA Consumer Surveys

Providing additional information on the proposed consumer research study for public comment will serve to "enhance the quality, utility, and clarity of the information to be collected."[5] It will also further the goals of the Paperwork Reduction Act ("PRA"). A stated purpose of PRA is to "ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government."[6] Providing more detailed information for public comment will provide benefits similar to those of the peer review process; for example, by calling attention to issues FDA may not have considered.

As is the case with the above-cited examples of food and drug industry comments on the FDA consumer surveys, JTI USA and its affiliates have valuable experience and expertise that can help refine FDA's effort to design a valid and reliable consumer survey regarding presentation of HPHC information to the public.

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[2] 75 Fed. Reg. 80821 (Dec. 23, 2010).

[3] 76 Fed. Reg. 30725 (May 26, 2011).

[4] 76 Fed. Reg. 20675 (Apr. 13, 2011).

[5] 76 Fed. Reg. 77837 (Dec. 14, 2011).

[6] 44 U.S.C. § 3501(2).

By providing more specific information about the study protocol, screener and questionnaire, FDA will "minimize the cost to the Federal Government of the creation, collection, maintenance, use, dissemination, and disposition of information."[7] Moreover, allowing additional comment on the study will assist FDA in fine-tuning the protocol and questionnaire before conducting the study with 60 panel members for pre-testing, 10,000 respondents to complete a screener, and 3,000 participants to complete the full study for an estimated total burden of 1,697 hours.

We appreciate FDA's consideration of our suggestion as it moves forward with the proposed study. Please feel free to contact me with questions or comments.

Respectfully Submitted,

Paisley Cameron

Director, Scientific &
Regulatory Affairs, Americas

JT International U.S.A., Inc.

[7] *Id.* § 3501(5).