

APPENDIX 1

60-Day Federal Register Notice

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.

Extra Label Drug Use in Animals—21 CFR Part 530 (OMB Control Number 0910-0325—Extension)

The Animal Medicinal Drug Use Clarification Act of 1994 allows a

veterinarian to prescribe the extra-label use of approved new animal drugs. Also, it permits FDA, if it finds that there is a reasonable probability that the extra-label use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extra-label use of the drug, and to require the development of an analytical method for the detection of residues above that established safe level. Although to date, we have not established a safe level for a residue from the extra-label use of any new animal drug, and therefore, have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are

therefore estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State, or Federal and/or State Agencies, academia, or individuals.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
590.22(b)	2	1	2	4,160	8,320

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

Dated: August 10, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0568]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study: Disease Information in Branded Promotional Material

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 research entitled "Experimental Study: Disease Information in Branded Promotional Material." The proposed research will explore the nature of

including information about a disease and promotional information about a specific drug treatment in the same advertising piece.

DATES: Submit either electronic or written comments on the collection of information by October 17, 2011.

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., P150-400B, Rockville, MD 20850, 301-796-3972, Elizabeth.Berbakos@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 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: Disease Information in Branded Promotional Material—(OMB Control Number 0910-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(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(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 prescription drug advertisements to contain accurate information about the benefits and risks of the drug advertised. Generally, the advertising must not be misleading about the effectiveness of the drug. Specifically, the ad must not contain a representation or suggestion that the drug is better than has been shown by substantial evidence or useful in a broader range of patients.¹ The regulations prohibit sponsors from, for example, disseminating promotional information that may broaden the indications of medications beyond the indication for which they have been approved. This regulation is designed to avoid misleading the audience by overpromising the outcomes of a particular drug and also to maintain a level playing field among competitors.

As a public health agency, FDA encourages the communication of accurate health messages about medical conditions and treatments. One way in which broad disease information is communicated to the public is through disease awareness communications:

"Disease awareness communications are communications disseminated to consumers or health care practitioners that discuss a particular disease or health condition, but do not mention any specific drug or device or make any representation or suggestion concerning a particular drug or device. Help-seeking communications are disease awareness communications directed at consumers. FDA believes that disease awareness communications can provide important health information to consumers and health care practitioners, and can encourage consumers to seek, and health care practitioners to provide, appropriate treatment. This is particularly important for under-diagnosed, under-treated health conditions, such as depression, hyperlipidemia, hypertension, osteoporosis,

¹ See 21 CFR 202.1(e)(6): "An 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: (i) Contains 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 patients (as used in this section, 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 (c) of this section) whether or not such representations are made by comparison with other drugs or treatments * * *"

and diabetes. Unlike drug and device promotional labeling and prescription drug and restricted device advertising, disease awareness communications are not subject to the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA regulations."²

Some research has shown that disease awareness advertising is viewed by consumers as more informative and containing less persuasive intent than full product advertising.³

Sponsors may choose to include disease information in their full product promotions. Such information is designed to educate the patient about his or her disease condition. However, in some cases a full description of the medical condition may include information about specific health outcomes that are not part of a drug's approved indication. The current project is designed to determine if providing such information in branded full product advertisements affects perceptions of the product.

When broad disease information accompanies or is included in an ad for a specific drug, consumers may mistakenly assume that the drug will address all of the potential consequences of the condition mentioned in the ad by making inferences that go beyond what is explicitly stated in an advertisement.⁴ For example, the mention of diabetic retinopathy in an advertisement for a drug that lowers blood glucose may lead consumers to infer that the drug will prevent diabetic retinopathy, even if no direct claim is made. The advertisement may imply broader indications for the promoted drug than are warranted, leading consumers to infer effectiveness of the drug beyond the indication for which it was approved. If consumers are able to distinguish between disease information and product claims in an ad, then they will not be misled by the inclusion of disease information in a

branded ad. If consumers are unable to distinguish these two, however, then consumers may be misled into believing that a particular drug is effective against long-term consequences. The current study will explore perceptions that result from including both disease information and promotional information about a specific drug in the same advertising piece.

Design Overview: We will investigate the effects of adding disease information to branded promotional materials on consumer perceptions and understanding. Disease information will be examined in the context of direct-to-consumer (DTC) prescription drug print advertisements. We hope to more readily generalize our findings by exploring the issues raised above in three medical conditions varying in severity and symptomatology. For example, disease information in a category such as oncology may be viewed differently than a mild skin condition or a non-symptomatic condition such as high cholesterol.

We plan to examine two variables in this study: The type of disease information in the piece (information about the disease and its possible outcomes, versus information about the disease without outcomes, versus no information about the disease) and the format of the information (integrated with drug information versus separated). Some participants will see information about the disease that avoids discussion of disease outcomes the drug has not been shown to address, such as, "Diabetes is a disease in which blood sugar can vary uncontrollably, leading to uncomfortable episodes of high or low blood sugar." Other participants will see disease information that mentions consequences of the disease that go beyond the indication of the advertised product, such as, "Untreated diabetes can lead to blindness, amputation, and, in some cases, death." We will also examine the way in which the disease information is presented relative to the product claims in the piece by varying the format: Disease information mixed (integrated) with product claims versus disease information apart (separated) from product claims. This study is experimental in method and utilizes random assignment to conditions. Within medical condition, participants will be randomly assigned to see one version of the ad. Participants will be recruited from a general population sample to control for prior knowledge about disease outcomes.

² See Draft Guidance for Industry: "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms" (p. 1), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070068.pdf>. Last accessed February 16, 2011.

³ Lee-Wingate, S. and Y. Xia, "Consumer perceptions of product-claim versus help-seeking direct-to-consumer advertising." *International Journal of Pharmaceutical and Healthcare Marketing*, 4(3), 232-246, 2010.

⁴ Burke, R.R., W.S. DeSarbo, R.L. Oliver, and T.S. Robertson, "Deception by implication: An experimental investigation." *Journal of Consumer Research*, 14(4), 483-494, 1988; Harris, R.J., "Comprehension of pragmatic implication in advertising." *Journal of Applied Psychology*, 62, 603-608, 1977; Jacoby, J., and W. Hoyer, "The comprehension and miscomprehension of print communications." New York: The Advertising Educational Foundation, 1987.

The preliminary design is included as follows:

TABLE 1—STUDY DESIGN

Medical condition	Disease outcome information	Format of disease information		Control (no disease information)
		Integrated	Separated	
Condition A	No Outcomes			
	Outcomes			
Condition B	No Outcomes			
	Outcomes			
Condition C	No Outcomes			
	Outcomes			

FDA estimates the burden of this collection of information as follows: We estimate the response burden to be 20 minutes in the pretests and the study,

for a burden of 1,985 hours. This will be a one time (rather than annual) collection of information. The questionnaire is available upon request.

The response burden chart is listed as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN⁵

Activity	Number of respondents	Number of responses per respondent	Total annual respondents	Average burden per response	Total hours
Screener	6,750	1	6,750	0.03 (2 min.)	203
Pretests	900	1	900	0.33 (20 min.) ...	297
Study	4,500	1	4,500	0.33 (20 min.) ...	1,485
Total					1,985

Dated: August 11, 2011.
 Leslie Kux,
 Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
 [Docket No. FDA-2011-N-0183]
Hung Ta Fan: Debarment Order
AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarbing Hung Ta Fan for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on

⁵ There are no capital costs or operating and maintenance costs associated with this collection of information.

a finding that Mr. Fan was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food. Mr. Fan was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of July 13, 2011 (30 days after receipt of the notice), Mr. Fan had not responded. Mr. Fan's failure to respond constitutes a waiver of his right to a hearing concerning this action.
DATES: This order is effective August 16, 2011.
ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
FOR FURTHER INFORMATION CONTACT: Kenny Shade, Office of Regulatory Affairs (HFC-230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-4640.
SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to

debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On August 4, 2010, the United States District Court for the Northern District of Illinois accepted Mr. Fan's guilty plea and entered judgment against him for the offense of conspiracy, in violation of 18 U.S.C. 371 and 2, for conspiring to defraud the United States and to violate 18 U.S.C. 542 (entry of Goods into the United States by means of false statements) and 18 U.S.C. 545 (importation contrary to law).

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the importation into the United States of any food. The factual basis for this conviction is as follows: In or around March 2005 and continuing until in or around November 2006, in violation of 18 U.S.C. 371 and 2, Mr. Fan agreed and conspired with others to defraud the United States and