

is, viewers will see the statement in all DTC ads for all products. In this study, we want to avoid the suggestion that there is something particular about the high blood pressure drug class that causes the statement to be mandated. Thus, we will show multiple DTC ads but ask questions regarding only the ad which has been manipulated to test our hypotheses. To maximize response information, the test ad will always be the last ad participants see.

After viewing the ads, a structured interview will be conducted. Participants will answer questions about the high blood pressure DTC test ad they have seen. Questions will examine a number of important perceptions about the advertised product, including risk comprehension, risk recall, benefit comprehension, benefit recall,

behavioral intention, noticeability of the toll-free statement, and comprehension of the toll-free statement.

Finally, demographic and health care utilization information will be collected. The entire procedure is expected to last approximately 15 minutes. A total of 1,600 interviews will be completed. This will be a one-time (rather than annual) information collection.

Participants

Data will be collected using an Internet protocol. Consumers over the age of 18 will be screened and recruited by the contractor to represent a range of education levels. Because the task presumes basic reading abilities, all selected participants must speak English as their primary language.

FDA proposes to conduct 2 rounds of pretesting with 200 consumers in each

round to refine the questionnaire and the stimuli before fielding the main study.

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

FDA estimates that 2,400 individuals will need to be screened to obtain a respondent sample of 400 for the pretests and 1,600 for the study. The screener is expected to take 30 seconds, for a total screener burden of 20 hours. The ad viewing and questionnaire are expected to take 15 minutes for the participants in the pretest and the main study, for a cumulative study burden of 500 hours. The estimated total burden for this data collection effort is 520 hours. The respondent burden is provided in table 1 of this document:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

| No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 2,400 (screener) | 1 | 2,400 | .008 | 20 |
| 400 (pretest) | 1 | 400 | .25 | 100 |
| 1,600 (study) | 1 | 1,600 | .25 | 400 |
| Total | | | | 520 |

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: November 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0597]

Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed; 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 #195, entitled “Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed.” This small entities compliance guide aids renderers in complying with the requirements of the final rule published in the **Federal Register** of April 25, 2008 (73 FR 22720). FDA’s goal is to strengthen existing safeguards to prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle and to reduce the risk of human exposure to the BSE agent.

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 written or electronic comments on the draft guidance by January 26, 2009.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-

addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Shannon Jordre, Division of Compliance, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9229, Shannon.jordre@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #195, entitled “Draft Guidance for Industry: Small Entities Compliance Guide for Renderers—Substances Prohibited From Use in Animal Food or Feed.” In the **Federal Register** of April 25, 2008 (73 FR 22720), FDA published a final rule entitled “Substances Prohibited From Use in Animal Food or Feed.” This

regulation is designed to further strengthen existing safeguards against the establishment and amplification of BSE, sometimes referred to as "Mad Cow Disease," through animal feed. The regulation prohibits the use of certain cattle origin materials in the food or feed of all animals.

FDA has prepared this draft Small Entities Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121). This document is intended to provide guidance to small businesses on the requirements of Title 21, Code of Federal Regulations, new § 589.2001 and amended § 589.2000.

II. Significance of Guidance

FDA is issuing this small entities compliance guide as a level 1 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 this topic. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information 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 589.2001 have been approved under OMB Control Number 0910–0627.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket

management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: November 20, 2008.

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0038]

Sex Differences in the Cardiovascular Device Trials; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "Sex Differences in the Cardiovascular Device Trials." FDA is co-sponsoring the conference with the Advanced Medical Technology Association (AdvaMed). The purpose of the workshop is to facilitate discussion between FDA and other interested parties on the study and analysis of sex and gender differences in cardiovascular medical device trials, in anticipation of issuance of draft guidance on this subject.

DATES: The workshop will be held on December 9, 2008, from 9 a.m. to 5 p.m. Participants are encouraged to arrive early to ensure time for parking and security screening before the meeting. Security screening will begin at 8 a.m. and reception will begin at 8:30 a.m. Please register by December 2, 2008, using the instructions in this document. Non-U.S. citizens are subject to additional security screening and should register as soon as possible.

ADDRESSES: The workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., rm. 230D, 240-276-4182, Rockville, MD 20850, kathryn.ocallaghan@fda.hhs.gov; or

Ashley Boam, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., rm. 230J, 240-276-4188, Rockville, MD 20850, ashley.boam@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Why Are We Holding This Public Workshop?

The purpose of the public workshop is to facilitate discussion between FDA and other interested parties on the study and analysis of sex and gender differences in cardiovascular medical device trials, in anticipation of issuance of draft guidance on this subject.

II. What Are the Topics We Intend to Address at the Public Workshop?

We hope to discuss a large number of issues at the public workshop, including, but not limited to:

- Current FDA perspective on sex/gender differences in pharmaceutical and medical device evaluation.
- Medical device development in the U.S. regulatory environment.
- Sex/gender-specific considerations in product design and clinical study design.
- The current state of cardiovascular treatment for women.
- Referral biases for women at risk for cardiovascular disease.
- The Clinical Research Organization and Institutional Review Board perspectives on inclusion, exclusion, recruitment, and retention issues related to women in clinical trials.
- The investigator/clinician perspective on the impact of sex/gender-specific issues on study design and conduct and available treatment options and limitations of use in women.
- The female patient perspective on enrollment and participation in clinical trials.
- The biostatistician perspective on statistical approaches and subgroup analysis in significant subpopulations.
- Case studies on gender-specific trials.

III. Is There a Fee and How Do I Register for the Public Workshop?

There is a modest fee to attend the conference to defray the costs of meals provided and other expenses. The fee for the meeting for registrants from industry is \$125.00, and the fee for government registrants is \$75.00. Fees will be waived for invited speakers and panelists. The registration process will be handled by AdvaMed, which has extensive experience in planning, executing, and organizing educational meetings. Register online at <http://www.AdvaMed.org>. Although the