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FDA is issuing this small entities compliance guide as a level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic.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This draft guidance refers to previously approved collections of information found in FDA regulations.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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.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.

[FR Doc. E8–28189 Filed 11–25–08; 8:45 am]

BILLING CODE 4160–01–S

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

facility is spacious, registration will be on a first-come, first-served basis. Non-U.S. citizens are subject to additional security screening, and should register as soon as possible.

If you need special accommodations because of a disability, please contact Kathryn O'Callaghan at least 7 days before the public workshop.

IV. Where Can I Find Out More About This Public Workshop?

Background information on the public workshop, registration information, the agenda, information about lodging, and other relevant information will be posted, as it becomes available, on the Internet at *http://www.AdvaMed.org* and *http://www.fda.gov/cdrh/dsma/workshop.html*.

Dated: November 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–28169 Filed 11–25–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program Patient Data Collection Form—NEW

The purpose of the Patient Navigator Outreach and Chronic Disease Prevention (PN) Demonstration Program is to promote model ''patient navigator'' programs to improve health care outcomes for individuals with cancer and/or other chronic diseases, with a specific emphasis on health disparity populations. This program aims to coordinate comprehensive health services for patients in need of chronic disease care and management through enhanced chronic disease management provided by patient navigators.

In order to describe successful PN program models and make recommendations on the ability of such programs to improve patient outcomes, data is needed at the individual patient, patient navigator, and PN program levels. This information includes:

- Sociodemographics of patients (*e.g.*, insurance status, income, education level, gender, age, race and ethnicity, primary language, number of family dependents) served;
- Patient access barriers to standard chronic disease care (*e.g.*, access to pharmaceuticals, distance of patient's home from health care facilities utilized, primary mode of transportation to health care facilities utilized, cultural and linguistic barriers as well as literacy levels);
- Health care service utilization (*e.g.*, screening rates, compliance rate for appointments and follow-up exams, time interval between diagnosis or referral and resolution date);
- Patient health status (*e.g.*, type and stage of diagnosis, chronic disease status, final outcome or result); and
- Patient navigation data (*e.g.*, type of navigator, patient navigation training plans and outcomes, point at which patient navigator was brought into the process, number of patients referred, how patient barriers were resolved, patient satisfaction, follow-up outcomes—such as number of uninsured who get health coverage).

This information will be collected from patients or their designated caregiver, patient navigators, and PN program administrators. Maintaining confidentiality of patient medical information is a concern and thus all personal information will be de-identified to protect the confidentiality of all patients. Data collection and disclosure processes will abide by Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule provisions and procedures. The estimated annual burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient [1] Data Intake Form	6,000	1	6,000	0.5	3,000
Navigated Patient Satisfaction Survey	6,000	1	6,000	0.25	1,500
SubTotal—Patient Burden	6,000	2	1,2000	0.75	4,500
Patient Navigator Survey	30	1	30	0.25	7.5
Patient Navigator Encounter/Tracking Log [2]	30	750	22,500	0.25	5,625
SubTotal—Patient Navigator Burden	30	751	22,530	0.5	5,632.5
Grantee PN Administrative Records [3]	6	1	6	0.5	3
Medical Record and Clinic Data [4]	6	2,000	12,000	2	24,000
SubTotal—Grantee Burden	12	2,001	12,012	2.5	24,006
Total Average Annual Burden	6,052	2,754	54,052	3.75	36,016

[1] Estimated number of navigated patients per year based on applications was rounded to 6000. See table below for projected numbers navigated by Grantee.

[2] Assumes 5 log entries of PN activities per patient.