Circulation 96:3647–3654, 1997 (subsequently referred to as the ''*Circulation* paper'') as representing changes in intracellular calcium concentration of pulmonary artery cells induced by ryanodyne and hypoxia.

VII. Dr. Gelband falsified electrophysiological records by reusing the same current-voltage trace as the resonse of renal vascular cells exposed for 2 seconds to Angiotensin II (Figure 4C) and to Caffeine (Figure 4B) on p. 124 of the publication Gelband, C.H. & Hume J.R. ''$[Ca^{2+}]_i$ Inhibition of K^+ Channels in Canine Renal Artery. A Novel Mechanism for Agonist-Induced Membrane Depolarization.'' *Circulation Research* 77(1):121–130, 1995 (subsequently referred to as the ''*Circ. Res.* 1995 paper'').

Dr. Gelband also submitted the falsified data above in Figure 4 in NIH grant application R29 JL52189–01A2.

VIII. Dr. Gelband fabricated laboratory research records for four Western blot experiments during the investigation, withholding from the institution his associate's notebook from which he had removed four labeled autoradiographic films from separate and different experiments, and using the removed films to fabricate a laboratory notebook containing falsified Western blots, which he provided to UF as evidence that he had conducted the experiments under investigation.

The terms of this Agreement are as follows:

(1) Respondent agreed to exclude himself voluntarily from any contracting or subcontracting with any agency of the United States Government and from eligibility or involvement in nonprocurement programs of the United States Government referred to as ''covered transactions'' as defined in the debarment regulations at 45 CFR part 76, for a period of ten (10) years, beginning on October 3, 2003.

(2) Respondent agreed to exclude himself voluntarily from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant, for a period of ten (10) years, beginning on October 3, 2003.

(3) Within 30 days of the effective date of this Agreement, Respondent agreed to submit letters of retraction to the following journals concerning the specified data in the listed articles:

A. *Hypertension* 2000 paper #1: Figures 5, 6, and 7 merited retraction. A retraction has been submitted relevant to this paper.

B. *Hypertension* 2000 paper #1: Figure 1A merited retraction. A retraction has been submitted relevant to this paper.

C. *JBC* paper: Figure 2 and Figure 4 merited retraction. It has already been withdrawn.

D. *Hypertension Online* paper: Figure 4A and Figure 3 merited retraction. It has already been withdrawn.

E. *Hypertension* 1999 paper: Figure 3 must be retracted.

F. *PNAS paper:* Figure 4A and 4B must be retracted.

G. *Circ. Res. 1999 paper:* Figure 5A must be retracted.

H. *Circ. Res. 1995 paper:* Figure 4C or 4B must be retracted.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

[FR Doc. 03–28197 Filed 11–7–03; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

The Board of Scientific Counselors (BSC), Agency for Toxic Substances and Disease Registry

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following subcommittee and committee meetings.

Name: Board of Scientific Counselors, ATSDR.

Times and Dates: 1 p.m.–5:30 p.m., December 1, 2003; 8:30 a.m.–4:30 p.m., December 2, 2003.

Place: Hilton Atlanta Hotel, 255 Courtland Street, NE., Atlanta, Georgia 30303.

Status: Open to the public, limited by the available space. The meeting room accommodates approximately 100 people.

Purpose: The Board of Scientific Counselors, ATSDR, advises the Secretary, and the Administrator, ATSDR, on ATSDR programs to ensure scientific quality, timeliness, utility, and dissemination of results. Specifically, the Board advises on the adequacy of science in ATSDR-supported research, emerging problems that require scientific investigations, accuracy and currency of the science in ATSDR reports, and program areas to emphasize or de-emphasize. In addition, the Board recommends research programs and conference support for which the Agency awards grants to universities, colleges, research institutions, hospitals, and other public and private organizations.

Matters To Be Discussed: The agenda items for the meeting will include, but are not limited to, an update and discussion on the consolidation of the National Center for Environmental Health (NCEH) and the Agency for Toxic Substances and Disease Registry (ATSDR); review of previous discussions for consolidating the Board of Scientific Counselors (BSC) for ATSDR and the Advisory Committee to the Director (ACD) for NCEH; a discussion on peer review background and process; introduction of the next two sessions on peer review; an overview of the National Exposure Registry; discussion of future role of BSC/ACD intramural program reviews, eligible programs for review, and program reviews in 2004; an overview of existing BSC and ACD subcommittees and working groups; review of the Community and Tribal Subcommittee Evaluation Report, Recommendations, and committee membership; discussion of the Social-Behavioral Science Workgroup's new strategic initiative; and a review of the Health Department Subcommittee on workforce development.

Agenda items are tentative and subject to change.

Contact Person for More Information: Robert Spengler, Sc.D., Executive Secretary, BSC, ATSDR, M/S E–28, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 404/498–0003.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATSDR.

Dated: November 4, 2003.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 03–28160 Filed 11–7–03; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0507]

Agency Emergency Processing Request Under OMB Review; Experimental Study of *Trans* Fat Claims on Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is an experimental study of *trans* fat claims on foods to evaluate the effects of various possible disclosure requirements to help consumers

understand and apply *trans* fat claims that they might see on food products. The study is intended to estimate the communication effectiveness of these disclosure requirements in realistic label usage situations for a range of products that may bear *trans* fat claims.

DATES: Fax written comments on the collection of information by December 10, 2003. FDA is requesting approval of this emergency processing by December 10, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is critical to the agency's mission of regulating food labeling and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320). Consumer education activities are needed to ensure the successful implementation of the regulation mandating disclosure of the *trans* fat amount on food label. Before these activities can be completed, it is necessary to resolve questions about possible accompanying disclosure requirements for *trans* fat nutrient content claims. Delays in resolving this issue will undercut the effectiveness of these activities and reduce the value of mandatory *trans* fat disclosure. For this reason, the use of normal clearance procedures would be likely to prevent or disrupt this collection of information.

FDA invites comments on: (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.

An Experimental Study of *Trans* Fat Claims on Foods

FDA is requesting OMB approval of an experimental study of *trans* fat claims on food products to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat claims on foods. In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA published an advance notice of proposed rulemaking entitled ''Food Labeling: *Trans* Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements.'' The document announced that the agency was seeking information about possible disclosure requirements to accompany nutrient content claims about *trans* fatty acids to help consumers make heart-healthy food choices. The proposed study is intended to evaluate the ability of several such disclosure requirements to enable consumer heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such disclosures and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from shopping mall intercept and Internet panel samples to evaluate how consumers understand and respond to claims on products with differing fatty acid profiles and possible disclosure requirements with those claims. The distinctive features of Internet panel and shopping mall methodologies for the purpose of this study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible disclosure statements label statements while controlling for individual differences. Random assignment ensures that mean differences between conditions can be tested using well known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. By implementing the study in a large nationally representative consumer panel with 600,000 households or in a geographically diverse set of shopping malls, the generalizability of the findings to a large fraction of the general population is also ensured.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to 1 of the 126 experimental conditions consisting of fully crossing 7 footnote disclosure conditions, 3 product types, 3 fatty acid profiles and 2 prior knowledge conditions.

Respondents will provide background information and respond to package labels that contain the variations of label statements to be tested. Key measures for the study are product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings).

FDA will use the information from the study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this study can be used by the agency to assess likely consumer responses to various disclosure requirements for nutrient content claims.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Internet survey	2,520	1	2,520	.4	1,008
Total					1,008

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

We anticipate that all statistical tests will collapse across the three product categories. We estimate that 20 subjects per cell, 2,520 subjects in all, will provide adequate power to identify small to medium size effects (i.e., r = .15 to .30) for all main effects and first order interactions with power = (1 - beta) well in excess of .80 at the .05 significance level. Power for second and third order interactions will necessarily be smaller, but even for third order interactions, statistical power will be =.80 at the .10 significance level.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28194 Filed 11–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0506]

Agency Emergency Processing Request Under Office of Management and Budget Review; Experimental Study of Possible Footnotes and Cuing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information is an experimental study of possible footnotes and cuing schemes to help consumers understand and apply quantitative *trans* fat information they might see on the Nutrition Facts panel (NFP) of a food product. The study is intended to estimate the communication effectiveness of these disclosure requirements in terms of the ability to help consumers make heart-healthy product decisions in realistic label usage situations for a range of products that will disclose quantitative *trans* fat information.

DATES: Fax written comments on the collection of information by December 10, 2003. FDA is requesting approval of this emergency processing by December 10, 2003.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: FDA is requesting emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is critical to the agency's mission of regulating food labeling and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations, 5 CFR part 1320. Consumer education activities are necessary to ensure the successful implementation of the regulation mandating disclosure of the *trans* fat amount on food label. Before these activities can be completed, it is necessary to resolve questions about accompanying footnotes and cuing schemes. Delays in resolving this issue will undercut the effectiveness of these education activities and reduce the value of mandatory *trans* fat disclosure. For this reason, the use of normal clearance procedures would be likely to prevent or disrupt this 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 of Possible Footnotes and Cuing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosure on the Nutrition Facts Panel (NFP)

FDA is requesting OMB approval of an experimental study of possible footnotes and cuing schemes to help consumers interpret quantitative *trans* fat disclosure on the NFP to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure. In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA published an advance notice of proposed rulemaking entitled ''Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,'' stating that the agency is seeking information about whether it should consider statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use disclosed information on the label to make healthy food choices. The proposed study is intended to evaluate the ability of several possible footnotes and cuing schemes to enable consumer heart-healthy food choices in order to provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from shopping mall intercept and Internet panel samples to evaluate how consumers understand and respond to possible footnotes and cuing schemes. The distinctive features of internet panel and shopping mall methodologies for the purpose of the study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible footnotes and cuing schemes while controlling for individual differences between subjects. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of effect size. By implementing the study in a large nationally representative consumer panel with 600,000 households or in a geographically diverse set of shopping malls, the generalizability of the findings to a large fraction of the general population is ensured.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 42 experimental conditions consisting of fully crossing seven