possible footnotes/cuing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the study to evaluate regulatory and 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 to estimate consumer comprehension and behavioral impact of various footnotes and cuing schemes intended to enable better understanding of quantitative *trans* fat information.

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	1,004
Total					1,004

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

We estimate that 60 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. 03–28195 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–0509]

Agency Emergency Processing Under Office of Management and Budget Review; Experimental Study of Health Claim Disclaimers 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 health claims on food product labels to evaluate the communication effectiveness of various possible labeling statements (i.e., disclaimers) to convey differing levels of scientific support for health claims. The study examines the communication effectiveness of disclaimers in realistic label use situations for a range of health claims and associated food products that may bear such health 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 (44 U.S.C. 3507(j) and 5 CFR 1320.13). The information is critical to the agency's mission of regulating food labeling. Currently FDA is operating under interim procedures for reviewing qualified health claims on conventional foods and dietary supplements (''Guidance for Industry and FDA: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements,'' that published in the **Federal Register** of July 10, 2003 (68 FR 41387–41390)). This interim approach was necessitated by various developments since the passage of the Nutrition Labeling and Education Act (NLEA), including successful legal challenges based on the First Amendment. The interim procedures provide guidance to industry regarding how the agency will respond to qualified health claims until the agency can promulgate notice-and-comment rulemaking. However, guidance documents do not establish legally enforceable responsibilities and are intended only as recommendations.

The interim procedures strain the agency's limited resources for reviewing qualified health claims. Qualified health claims greatly increase the number of potential health claims and as a result the agency anticipates a far greater number of health claim petitions. The agency included criteria for prioritizing petitions in order to maximize the public health benefit of its interim qualified health claim procedure, which will necessitate delays for some petitions. The interim guidance also creates uncertainty for industry, since qualified health claims are permitted through a letter of enforcement discretion, and are not authorized through a regulation. This is likely to inhibit some companies from submitting petitions during the interim period. FDA prefers that this interim period be as short as possible.

Consumer data are important to the development of new regulations for health claims. A central consideration in the development of a new regulatory framework for qualified health claims is the importance of ensuring that such claims can be made in a way that is not misleading to consumers. The agency recognizes that it is unknown whether consumers can distinguish between differing levels of scientific support and there are no consumer data currently available to assess the effectiveness of wording options proposed for conveying the different levels. The interim guidance relies on limited prior experience under a temporary policy of enforcement discretion, using ad hoc health claim disclaimers.

Given the uncertainties and constraints inherent with interim guidance and the absence of relevant consumer data to address questions raised by the new approaches to health

claims under consideration, we are seeking emergency approval of the proposed study in order to provide needed consumer data in time to assist the agency in developing new regulations for qualified health claims.

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 Health Claim Disclaimers on Foods

FDA is requesting OMB approval of an experimental study of health claims and disclaimers on food labels to help the Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for qualified health claims. Several possible approaches to implementing this qualified health claim scheme that differ in terms of the specific language and form of disclaimers used to convey level of scientific certainty are evaluated in terms of the ability of the proposed approach to accurately convey the actual level of scientific uncertainty for the stated claim.

The recent report of the FDA Task Force (Consumer Health Information for Better Nutrition Initiative Task Force Final Report, July 10, 2003) describes a four-level rating scheme for evaluating petitioned claims (consisting of unqualified claims that meet the standard of significant scientific agreement as defined by NLEA and three levels of qualified claims supported by decreasing levels of scientific evidence). The proposed consumer research is designed to test approaches to conveying levels of scientific uncertainty through the use of disclaimers that are linked to this four-level rating scheme for petitioned health claims.

The proposed study is intended to evaluate the effectiveness of several possible options for communicating the strength of scientific evidence for a given health claim across a range of health claims of varying scientific certainty. The evidence should provide empirical support for possible policy decisions about the need for disclaimers to minimize consumers' misunderstanding and misapplication of qualified health claims and the optimal language and the form such disclaimers should take. The impact of disclaimers is examined across a range of measures that capture what is conveyed about the state of scientific certainty for the claim as well as the impact of the qualified health claim on attributions about the food product that displays the claim.

FDA will conduct an experimental study using shopping mall intercept samples. The mall intercept methodology allows controlled presentation of visual materials, experimental manipulation of study materials, and the random assignment of participants to experimental conditions. The experimental manipulation of label conditions and random assignment to conditions allows for statistical estimates of the effects of different approaches to conveying level of scientific support and allows quantitative comparisons of the effectiveness of different forms and wording options for health claim disclaimers. Random assignment ensures that mean differences between conditions can be tested using established techniques such as analysis of variance and multiple regression analysis to yield statistically valid estimates of effect size.

The study design is based on the controlled presentation of realistic product labels that carry health claims for four nutrient/disease health claims. The four health claims that are tested vary in terms of the degree of scientific evidence underlying the health claim. Label conditions consist of different forms and specific wordings for disclaimers that accompany the nutrient/disease health claim as well as various control conditions that assess how consumers view the product and the scientific evidence in the absence of an explicit health claim on the product label.

Participants will be recruited using standard mall intercept methods, implemented in 6 geographically dispersed shopping malls. Participants are adults, aged 18 and older who do half or more of the grocery shopping for their household. Each site will have the same number of replicates of the experimental design that include all counterbalancing factors.

Four different schemes for communicating strength of science are tested: Point-Counterpoint (claim, followed by disclaimer), Embedded language (disclaimer first), Report Card (A-D letter ratings) and Graphic (graphic device to illustrate the rating scheme). Each scheme adopts the four-level strength of science ranking system described in the Interim Guidance.

The study includes four control conditions, representing important types of label statements and label users that constitute benchmarks for assessing the direction and magnitude of effects due to communications about the strength of scientific evidence for the health claims: (1) ''Tombstone'' control with no nutrient content or health claim, (2) nutrient content claim, but no health claim, (3) ''full information control'' in which the participant is provided with a summary of the scientific evidence for the claim prior to observing food labels and (4) expert controls, based on separate information gathered from nutrition experts knowledgeable about the diet-disease relationship.

The key measures for this study are the perceived strength of science for the claim that is conveyed by the label condition and product perception questions about the labeled food product (expected health benefits, perceived nutrition ratings) that identify the practical impact of the product label.

FDA will use the information from this study to guide the development of regulatory policy options related to qualified health claims. The agency acknowledges the lack of empirical data about how consumers understand and respond to statements they see in product labeling. The information gathered in this study can be used by the agency to assess likely consumer responses to various options for qualifying health claims based on varied levels of scientific evidence.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,920	1	1,920	.30	576

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

The approaches and wording options for qualified health claims of central interest to the agency requires a complex experimental design. To ensure adequate power to identify differences, the minimum cell size is 60 participants. This will be sufficient to identify small to medium 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.

Dated: November 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28196 Filed 11–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002P–0431]

Determination That Delcobese (Amphetamine Adipate, Amphetamine Sulfate, Dextroamphetamine Adipate, Dextroamphetamine Sulfate) Tablets and Capsules Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for generic versions of Delcobese tablets and capsules.

FOR FURTHER INFORMATION CONTACT: Aileen H. Ciampa, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under 314.161(a)(1) of the act (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) tablets (1.25 milligrams (mg), 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–563. Delcobese (amphetamine adipate, amphetamine sulfate, dextroamphetamine adipate, dextroamphetamine sulfate) capsules (1.25 mg, 2.5 mg, 3.75 mg, 5 mg) were the subject of approved ANDA 83–564. Both ANDAs were submitted by Delco Chemical Co., but ownership was later transferred to Lemmon Co. Delcobese tablets and capsules were labeled for the following indications: (1) Narcolepsy; (2) behavioral syndrome characterized by hyperactivity, distractability, and impulsiveness in children (currently commonly known as attention deficit hyperactivity disorder or ADHD); and (3) exogenous obesity. Prior to Delcobese's discontinuation, FDA proposed to remove the exogenous obesity indication from the labeling of all drug products containing an amphetamine, including Delcobese products, and offered the application holders an opportunity for hearing (44 FR 41552, July 17, 1979). That notice is still pending. While it is pending, the exogenous obesity indication may not be approved for ANDAs relying on Delcobese tablets or capsules as their listed drug (21 CFR 314.127(a)(9)).

On February 22, 1985, Lemmon Co. notified FDA that Delcobese capsules had not been manufactured since March 1984. On June 4, 1990, FDA requested that Lemmon Co. withdraw ANDAs 83–563 and 83–564 because the marketing of both Delcobese capsules and tablets had been discontinued. On February 24, 1993, Lemmon Co. requested the withdrawal of ANDAs 83–563 and 83–564. Accordingly, FDA withdrew approval of the applications in a **Federal Register** notice (58 FR 27737, May 11, 1993). Delcobese was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book.

In a citizen petition submitted under 21 CFR 10.30 dated September 20, 2002 (Docket No. 02P–0431), as amended by a letter dated October 23, 2002, Sonnenschein Nath & Rosenthal requested that FDA determine whether Delcobese tablets and capsules were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Delcobese tablets and capsules were not withdrawn from sale for reasons of safety or effectiveness. The petitioners identified no data or other information suggesting that Delcobese tablets and capsules were withdrawn from sale as a result of safety or effectiveness concerns. FDA has independently evaluated relevant data, including postmarketing adverse event reports, but