RECORD SOURCE CATEGORIES:

Information is obtained from departments, agencies, or instrumentalities of the United States or any State and from multi-state financial institutions.

ITEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 04–12506 Filed 6–2–04; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0246]

Agency Emergency Processing Under OMB Review; Experimental Study of Petitioned Health Claims on Glucosamine and Chondroitin Sulfate

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 in response to a petition for health claims for glucosamine and chondroitin sulfate. The study examines various petitioned health claims about the effect of glucosamine and chondroitin sulfate on osteoarthritis. The goal of the study is to determine if certain claims about glucosamine and/or chondroitin (the ''product'') and the reduction of risk of specific outcomes related to osteoarthritis, namely joint degradation and cartilage deterioration, create misperceptions on the part of consumers about the intended use of the product.

DATES: Fax written comments on the collection of information by July 6, 2004. FDA is requesting approval of this emergency processing by July 6, 2004.

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 health claims on dietary supplements. FDA has received petitions for new health claims for glucosamine and chondroitin sulfate. Unlike traditional health claims that promote the ability of a product to reduce the risk of a particular disease, the petitioned claims promote the ability of the product to reduce the risk of a specific health outcome without mention of an associated disease.

Traditionally, a health claim states how a product will reduce the risk of contracting a particular disease. An example of this type of claim would include ''Eating a diet rich in fruits and vegetables may reduce the risk of cancer.'' Here, the statement clearly defines the product (fruits and vegetables), its risk-reducing effect, and the disease upon which it may be effective (cancer). The petitioned claims, however, do not employ the standard structure as traditional health claims.

The petitioned claims are designed as health claims, in that they promote the risk reducing effect of glucosamine and chondroitin sulfate. The claims neglect, however, to mention the specific disease risk, or the risk of osteoarthritis, that the product intends to reduce. Instead, the claims mention symptoms, modifiable risk factors, and surrogate endpoints of the disease. An example of these claims is ''Glucosamine and chondroitin sulfate may reduce the risk of joint degradation.'' The petitioned claims to be examined resemble health claims by their use of language concerning the reduction of risk. Yet they employ terminology suggestive of modifiable risk factors of the disease, which are elements not traditionally found in health claims. It is not clear how consumers will interpret these claims. The agency is concerned that the label language may cause consumers to interpret the claims in such a way that would suggest it has an effect on the disease or condition other than risk reduction.

Consumer research is needed to test consumer's perceptions of claims that promote risk reduction of contracting a symptom or a modifiable risk factor for a disease. Despite the verbiage within the claim about risk reduction, the presence of health conditions without mention of a disease may cause consumers to believe that the product will treat the health condition rather than reduce risk. If consumers disregard language concerning the reduction of risk and interpret the claim as one that promotes a treatment effect, then the claim language has created a misperception on the part of the consumer. The result is that consumer's interpret the claim as a treatment claim rather than a health claim.

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.

Experimental Study of Petitioned Health Claims on Glucosamine and Chondroitin Sulfate

FDA is requesting OMB approval of an experimental study of petitioned health claims on glucosamine and chondroitin sulfate. The study examines various petitioned health claims about the effect of glucosamine and chondroitin sulfate on osteoarthritis. The goal of the study is to determine if certain claims about glucosamine/chondroitin (the ''product'') and the reduction of risk of specific outcomes related to osteoarthritis, namely joint degradation and cartilage deterioration, create misperceptions on the part of consumers about the intended use of the product. Results of the study will inform the Center for Food Safety and Applied Nutrition decision making process, particularly as it concerns the approval of the use of these claims. The results may also assist in future decisions toward other claims that bear similar characteristics.

The need for consumer research on various dietary supplement claims arises over a concern that consumer's may misinterpret or misperceive a health claim as a treatment claim when the claim does not clearly refer to a specific disease. Traditional health claims for dietary supplements promote the ability of a product to reduce the risk of a particular disease. However, new claims about products promote the ability of a product to reduce the risk of

a specific health outcome without mention of an associated disease. If the specific health outcome is mentioned without a disease, consumers may misunderstand the claim as one that promotes the product's ability to treat, and not reduce the risk of contracting, a particular health outcome.

The larger question of whether or not a consumer interprets a claim as a drug treatment claim or as a health claim will be answered by comparing the effect of various label claim language on a consumer's perceptions of the effect and potency of a product, and the time in which the product will be effective. This is accomplished by answering a number of smaller research questions about claims concerning glucosamine/chondroitin and their relationship to claims that could be made about food products, as well as their relationship to claims that could be made about an over-the-counter (OTC) or pharmaceutical drug.

The working hypothesis underlying the study design is that consumer's perceive dietary supplements as less potent, less effective, and therefore having a weaker effect on a health condition than drugs. A parallel hypothesis is that consumer's perceive dietary supplements as more potent, more effective, and therefore having a stronger impact on a health condition as food. The study is designed to assess the relative position of a dietary supplement product, ''DS'', with respect to a food and a drug along three dimensions characterizing the impact of the DS. These three dimensions include the type of effect the consumer believes the DS will have on a health condition, and the perceived effectiveness of the substance at achieving the claimed effect, and the time in which the consumer believes the effect will occur. The study will also assess how various types of claims on food products, drugs, and dietary supplements change how consumers perceive the relative position of these products with each other. The study will determine if the presence of a petitioned claim on the product label causes consumers to perceive the product as more treatment-like in its effect than when an approved health claim is present.

FDA will conduct an experimental study using subjects recruited from an internet panel of 500,000 households. The internet panel 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 information intended by the health claims. 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 glucosamine/chondroitin, as well as a food product and an OTC drug product. The various health claims that are tested vary in terms of the use of language concerning treatment or risk-reduction effects, and the use of terminology related to a disease or a symptom or risk factor of a disease. In addition, on some labels a disclaimer accompanies the claims. A number of labels will carry claims about the product's effect on a specific disease (osteoarthritis) and will serve as control conditions that assess how consumers view the product when the claims mention only symptoms of the disease.

Panel members are recruited by a variety of means designed to reflect all segments of the population. They are required to have a computer with Internet access. Typical panel members receive three or four invitations per month to participate in research projects. Incentives of small monetary value are given to panel members for their participation periodically.

Each participant in the study will examine one of the label products described earlier. The product may be a food, drug, glucosamine, chondroitin sulfate, or glucosamine/chondroitin combination. The study may also include an additional dietary supplement for comparison with the glucosamine and chondroitin product. The label will have a claim about the products effect on the reduction of risk of either osteoarthritis, joint degradation, or cartilage deterioration. The subject will answer a short set of questions related to each of the label products that they have been shown. These questions will pertain to the consumer's perception of the effect (treat/reduce risk) of the product, the relative effectiveness of the product, and the time in which the effect occurs (hours versus years).

The study includes three conditions, representing important types of label claims and label users that constitute benchmarks for assessing the direction and magnitude of effects due to the presence of symptom-like health conditions: (1) A control that is an approved or traditionally worded health claim, i.e., one that mentions risk reduction of a specific disease; (2) a petitioned health claim that mentions a symptom-like condition, but not the disease; and (3) a petitioned health claim with a disclaimer that states that the product is not intended to cure or treat a disease. The key measures for this study are the perceived effects of the product conveyed by the label condition, the effectiveness of the product, and the expected timeframe within which the product is expected to be effective.

FDA will use the information from this study to guide the decision making process concerning current and future petitions for 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]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1,560	1	1,560	0.16	250

[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: May 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12532 Filed 6–2–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0251]

Draft Guidance for Industry, Food and Drug Administration Staff, and Food and Drug Administration-Accredited Third-Parties: Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by the Medical Device User Fee and Modernization Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Requests for Inspection by an Accredited Person Under the Inspections by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002.'' Section 201 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) authorizes FDA-accredited third parties (accredited persons or APs) to conduct inspections of manufacturers of class II and class III devices who meet certain eligibility criteria as defined by the statute. This draft guidance document describes the establishment eligibility criteria and the process for establishments to follow when requesting FDA's approval to have an AP conduct an inspection of their establishment instead of FDA under the new inspections by accredited persons program (AP program).

DATES: Submit written or electronic comments on this draft guidance by September 1 2004. Submit comments on the collection of information by August 2, 2004.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Requests for Inspection Under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the guidance and collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the guidance and collection of information to: *http://www.fda.gov/dockets/ecomments*. Identify all comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For medical device issues: Casper E. Uldriks, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Road, Rockville, MD 20850 301–594–4692

For biologics issues: Carol Rehkopf, Center for Biologics Evaluation and Research (HFM–650) Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852 301–827–6202

SUPPLEMENTARY INFORMATION:

I. Background

MDUFMA (Public Law 107–250) added a provision in section 704(g) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374(g)) to permit third-party inspections of eligible establishments who market class II or class III devices in the United States and who also market or plan to market such devices in foreign countries. The new law also defines the qualifying criteria that a manufacturer must meet in order to participate in the AP program (section 704(g)(6)(A) of the act). This guidance will help manufacturers determine whether they are eligible to participate in this inspectional program and identifies the information manufacturers should submit to the agency when requesting permission to use an AP.

The AP program generally enables manufactures to better manage their inspection schedules since they will schedule the AP inspections themselves, provided FDA has approved their request to use an AP. Eligible firms, however, remain subject to inspections by FDA (section 704(g)(9) of the act). The program is voluntary; no manufacturer is required to participate, whether domestic or foreign.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on inspection requests under the AP program authorized by section 201 of MDUFMA. 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 statute and regulations.

III. Comments

Interested parties may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. 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.

IV. Electronic Access

To receive ''Requests for Inspection under the Inspection by Accredited Persons Program Authorized by Section 201 of the Medical Device User Fee and Modernization Act of 2002'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1532 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of cleared submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic