DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0063]

Agency Emergency Processing Request Under OMB Review; Consumer Surveys on Food and Dietary Supplement Labeling Issues

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 would consist of surveys to study consumers' understanding of labeling on conventional foods and dietary supplements as well as consumer practices, knowledge levels, and attitudes related to such labeling.

DATES: Submit written or electronic comments on the collection of information by March 25, 2002.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (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 and is needed prior to the expiration of the normal time periods for OMB clearance under the PRA regulations (5 CFR part 1320). The U.S. Constitution's first amendment impact on regulatory decisions on labeling necessitate prompt agency action to ensure that the constitutional rights of regulated entities are preserved. For this reason, the use of normal clearance procedures would be likely to prevent or disrupt this collection of information. Under section 903(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 393(d)(2)(C)), FDA is authorized to conduct research related to food labeling.

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.

Consumer Surveys on Food and Dietary Supplement Labeling Issues

FDA is requesting OMB approval of consumer surveys to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting the labeling of conventional foods and dietary supplements. Determining how consumers are likely to interpret various kinds of claims, disclaimers, warnings, caution statements, and notice statements that might appear in labeling is critical to agency decisionmaking under the act and the first amendment. It is often necessary to test actual or proposed labeling statements in realistic situations with typical consumers to determine what these label statements are communicating to consumers.

FDA or its contractor will collect and use information gathered from telephone, mail, shopping mall intercept, and Internet surveys to evaluate how consumers understand and respond to existing label statements, label statements proposed by industry or consumers, and other label statements that are under consideration as part of FDA's policy development process. Potential respondents to the surveys will be individual consumers either randomly chosen to represent specified populations or randomly assigned to experimental treatment conditions to control for the effects of individual differences in the population on the interpretation of label statements. In all instances, FDA will strive to collect a representative sample of individuals from the overall population or from relevant population groups, as appropriate. FDA's general selection method will use stratification, with random sampling within the strata, to achieve representativeness for both overall populations and sensitive subpopulations, such as at-risk individuals or user segments. In the rare cases where geography is a limiting factor, FDA will use population-based cluster sampling to limit government expense while preserving the statistical properties of the sample.

Respondents will provide background information and respond to package labels that contain the variations of label statements to be tested. Measures will include both self-reported comprehension and acceptance as well as direct behavioral measures of consumer use and understanding of the package labeling.

FDA will use the information from the surveys in evaluating regulatory and policy options with respect to labeling. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from such surveys can be used to test consumer comprehension and behavioral impact of various label statements and formats, and to identify the existing distribution of behavior, knowledge, and attitudes in the population that provides the context for understanding such statements. The surveys will help FDA assess consumer reactions to existing and proposed label statements.

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
Mail questionnaire	1,000	1	1,000	1	1,000
Telephone survey	2,000	1	2,000	.5	1,000
Internet or cable survey	4,000	1	4,000	.5	2,000

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					4,000

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

These estimates are based on the expected number of respondents necessary to obtain a statistically significant representation of important consumer segments (e.g., users of relevant regulated products, at-risk population groups), and the number of labeling options that may need to be tested.

Dated: February 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0028]

Medical Devices; Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA; 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 ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to reclassify cyclosporine and tacrolimus assays from class III to class II when used as an aid in the management of transplant patients. If these devices are reclassified, this draft guidance will serve as the special control for the reclassified devices. This draft guidance is neither final nor in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by April 22, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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 draft guidance. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFZ–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance was developed as a special controls guidance to support the proposed reclassification of cyclosporine and tacrolimus assays from class III to class II. When final, this guidance will replace the document ''Guidance Criteria for Cyclosporine PMAs'' dated January 24, 1992. That document was intended to cover the basic science, clinical experience, and issues identified through the review of premarket approval applications (PMAs) for cyclosporine. The agency has updated that guidance. The revised guidance has been retitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA.'' On its own initiative, the agency has included tacrolimus assays in addition to cyclosporine assays in the revised guidance because the tacrolimus assay has the same intended use as an aid in the management of transplant patients. The agency believes it is taking a least burdensome approach by including tacrolimus assays in the revised guidance and will include tacrolimus assays in the proposed reclassification.

II. Significance of the Guidance

The draft guidance, when finalized, will represent the agency's current thinking on cyclosporine and tacrolimus assays. 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 applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' via your 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 1380 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so 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 access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' will be available at http://www.fda.gov/cdrh/ode/guidance/1380.pdf.