DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0063]

Agency Information Collection Activities; Proposed Collection; Comment Request: 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on surveys to study consumers' understanding of specific label statements for conventional foods and dietary supplements and the impact of such labeling on consumer practices, knowledge levels, and attitudes. In the **Federal Register** of July 8, 2002 (67 FR 45128), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910–0492). Because this was an emergency approval that will expire on December 31, 2002, FDA in this notice is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information by December 2, 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 Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Consumer Surveys on Food and Dietary Supplement Labeling Issues (OMB Control Number 910–0492)—Extension

FDA is requesting an extension of the 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 Federal Food, Drug, and Cosmetic 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 or 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, taking into account 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 mall intercept survey	4,000	1	4,000	.5	2,000
Total					4,000

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

These estimates assume that as many as one mail survey project, one telephone survey project, and two internet or mall intercept survey projects may be done on an annual basis. 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: September 24, 2002..

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–25079 Filed 10–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 007'' (recognition list number: 007), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: The recognition of standards announced in this document will become effective October 2, 2002. Submit written comments concerning this document at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of ''Modifications to the List of Recognized Standards, Recognition List Number: 007'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Submit written comments concerning this document to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Identify comments with the docket number found in brackets in the heading of this document. You may access this document on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. See section V of this document for electronic access to the searchable database for the current list of ''FDA Recognized Consensus Standards,'' including recognition list number: 007 modifications, and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 156.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 of the act allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of guidance entitled ''Recognition and Use of Consensus Standards.'' This notice described how FDA will implement its standards program recognizing the use of certain standards and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617); July 12, 1999 (64 FR 37546); November 15, 2000 (65 FR 69022); May 7, 2001 (66 FR 23032), and January 14, 2002 (67 FR 1774), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA.

FDA maintains the agency's current list of ''FDA Recognized Consensus Standards'' in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and this recognition of consensus standards will be effective upon publication in the **Federal Register**. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

For each of the recognized standards, FDA provides in the database a supplementary information sheet that includes information such as:

1. Devices affected by the standard;
2. Processes affected by the standard (premarket notification (510(k), premarket approval (PMA), investigational device exemption (IDE), product development protocol (PDP), and quality systems regulation (QSR));
3. Extent of recognition (all or part of the standard, for what purpose the standard is recognized);
4. Related citations in the Code of Federal Regulations that identify the devices covered;
5. Related product codes that are used by FDA to identify the devices covered; and
6. Guidances relevant to the devices affected by the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 007

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency