SUPPLEMENTARY INFORMATION:

I. Purpose

Section 921 of the Public Health Service Act (42 U.S.C. 299c) established the National Advisory Council for Healthcare Research and Quality. In accordance with its statutory mandate, the Council is to advise the Secretary and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of the Agency to enhance the quality, improve outcomes, reduce costs of health care services, improve access to such services through scientific research, the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.

The Council is composed of members of the public appointed by the Secretary and Federal ex-officio members. Donald M. Berwick. M.D., the Council chairman, will preside.

II. Agenda

On Friday, November 3, 2000, the meeting will begin at 8:30 a.m., with the call to order by the Council Chairman. The Director, AHRQ, will present the status of the Agency's current research, programs and initiative. Tentative agenda items include evidence-based practice centers, patient safety, translating research into practice (T.R.I.P.), and Office of Priority Populations Research. The official agenda will be available on AHRQ's website at *www.ahrq.gov* no later than October 20, 2000. The meeting will adjourn at 4:00 p.m.

Dated: October 13, 2000.

John M. Eisenberg,

Director.

[FR Doc. 00–27104 Filed 10–20–00; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control And Prevention

[60Day–01–03]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995, the Center for Disease Control and Prevention is providing opportunity for public comment on proposed data collection projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

Telephone Survey Measuring HIV/STD Risk Behavior Using Standard Methodology—New—National Center for HIV, STD, Tuberculosis Prevention (NCHSTP), CDC. The goal of the overall project is to conduct testing of a set of survey questions intended to obtain measures of risk behaviors for Human Immunodeficiency Virus (HIV) and Sexually Transmitted Diseases (STDs). This proposed data collection is for the second phase of this 2-year project. During the first phase questions were developed and tested, and a pretest of 203 interviews was conducted. During this second phase a pilot survey with a larger number of respondents will be conducted, and a small number of additional questions will be included measuring HIV-related stigma.

Knowledge about the level of HIV risk behaviors in populations is essential for effective HIV prevention programs. Currently, survey-based assessment of these behaviors depends on a range of survey questions that differ across surveys, and that are difficult to compare and to reconcile. Therefore, the Behavioral Surveillance Working Group, coordinated by the National Center for HIV, STD and Tuberculosis Prevention, Centers for Disease Control and Prevention, has developed a draft set of items to be proposed as standard survey questions on the topics of sexual behavior, HIV testing, drug use, and other behaviors related to risk of contracting HIV and/or STDs. As part of this effort, CDC will sponsor a telephone-based pilot of 400 persons aged 18–59, selected randomly from within an urban area, in order to test these questions.

Further, because some of the survey questions are private and potentially sensitive, the project will entail the testing of a survey administration mode: Telephone-based audio computer-assisted self-interview (T–ACASI), in which a computer will be used to administer the most sensitive questions, and in which the surveyed individual enters responses directly onto the telephone keypad. This procedure eliminates the need for communication of sensitive questions from the interviewer to the respondent, as well as the need for respondents to answer the questions verbally. In order to test the effectiveness of this procedure, half of the interviews will be conducted using the T–ACASI procedure for the most sensitive questions, and half using standard, interviewer-based administration of all questions. Data analysis will rely on an assessment of the response rate under each mode, and on the nature of the data obtained to the sensitive questions. The larger sample size of the year 2 pilot survey will enable us to test statistical significance of the effectiveness of the T–ACASI procedure.

Information and data obtained from this evaluation will help direct future surveys, by determining whether it is feasible to attempt to administer these standard risk questions using a telephone survey, and whether a T–ACASI-based procedure represents a technological innovation that will positively contribute to such an effort, through improvements in data quality. The total cost to respondents is $1355.52.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response (in hours)	Total burden (in hours)
Screening	1872	1	0.02	37.4
Interview	400	1	0.33	132.0

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden per response (in hours)	Total burden (in hours)
Total Burden				169.4

Dated: October 17, 2000.

Nancy Cheal,

Acting Associate Director for Policy, Planning, and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–27118 Filed 10–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N 0044]

Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Availability of Citizen Petitions for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comment of three petitions submitted by Hyman Phelps & McNamara (HP&M), the American Herbal Products Association (AHPA), and jointly by the Council for Responsible Nutrition (CRN) and the Consumer Healthcare Products Association (CHPA). The petitions requested, among other things, that dietary supplements be permitted to make claims about effects on the structure or function of the body that are derived from nutritive value without being subject to the disclaimer and notification requirements of the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written comments on the petitions by December 22, 2000.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA 305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Electronic comments may be submitted via the Internet at www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm or via e-mail: fdadockets@oc.fda.gov. All comments should be identified with the docket number found in brackets in the heading of this document. The petitions are available for review at the Dockets Management Branch (address above) or electronically on the agency's website at http//www.fda.gov/ohrms/dockets/dockets.htm. You may also request copies of the petitions from the Dockets Management Branch.

FOR FURTHER INFORMATION CONTACT: Rhonda Rhoda Kane, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS 821), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 6, 2000 (65 FR 1000), in the preamble to its final rule entitled ''Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body,'' FDA stated that dietary supplements bearing structure/function claims must comply with the notice, disclaimer, and other requirements of section 403(r)(6) of the act (21 U.S.C. 343(r)(6)). More specifically, the agency stated:

Section 403(r)(6) of the act, by its terms, applies to dietary supplements. The other possible source of authority to make structure/function claims on dietary supplements is section 201(g)(1)(C) of the act, which provides that ''articles (other than food) intended to affect the structure or any function of the body of man or other animals'' are drugs. Under this provision, foods may make claims to affect the structure or function of the body without being regulated as drugs. By its terms, however, section 201(g)(1)(C) of the act exempts a dietary supplement that bears a structure/function claim from drug regulation only if it is also a food. The last sentence of section 201(ff) of the act provides, ''Except for purposes of section 201(g), a dietary supplement shall be deemed to be a food within the meaning of this Act.'' The clear import of this language is that dietary supplements are not foods under section 201(g) of the act and therefore cannot qualify for the ''(other than food)'' exception to the drug definition in section 201(g)(1)(C). As a result, dietary supplements that use structure/function claims may do so only under section 403(r)(6) of the act and are therefore subject to the disclaimer, notification, and other requirements in that section and in FDA's implementing regulation. 65 FR 1000 at 1033.

The preamble acknowledged that this conclusion reverses a position stated in the **Federal Register** of September 23, 1997 (62 FR 49859), in the final rule entitled ''Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements.'' The preamble to that rule stated that a dietary supplement could bear a structure/function claim under the ''(other than food)'' exception to the drug definition in section 201(g)(1)(C) of the act (21 U.S.C. 321(g)(1)(C)), provided that the claim was truthful, nonmisleading, and derived from nutritive value (see 62 FR 49859 at 49860, 49863, and 49864). The reversal was based on reconsideration of the plain language of section 201(ff) of the act.

II. The Citizen Petitions

On February 4, 2000, HP&M filed a petition requesting, among other things, that the agency reconsider and revoke its ''pronouncement'' in the January 6, 2000, final rule that all structure/function claims in the labeling of dietary supplements must use the section 403(r)(6) of the act disclaimer and notification procedures. The petition further requests that FDA reinstate its previous position that a structure/function claim in the labeling of a dietary supplement product need not comply with the disclaimer and notification requirements if the claim is truthful, nonmisleading, and derived from nutritive value.

Citing *United States* v. *Ten Cartons * * **Ener-B Vitamin B 12*, 72 F.3d 285, 287 (2d Cir. 1995), HP&M argues that section 201(g)(1)(C) of the act must be applied without reference to section 201(ff) of the act. In sum, HP&M states that the effect of section 201(ff) of the act ''is merely that a dietary supplement will not ''automatically qualify as food.''' HP&M further argues that whether or not a particular dietary supplement qualifies as food is determined by *Nutrilab, Inc.* v. *Schweiker*, 713 F.2d 335 (7th Cir. 1983). That case held that a product is a food if it is used primarily for ''taste, aroma or nutritive value.'' *Nutrilab*, 713 F.2d at 338. For example, the petition argues