SUMMARY: The Office of Disease Prevention and Health Promotion (ODPHP), Office of Public Health and Science, Department of Health and Human Services (HHS), acting on behalf of an ad hoc Federal working group, is soliciting written comments on a proposed definition of ''bioactive food components.''

DATES: Submit written or electronic comments by November 1, 2004.

ADDRESSES: Submit a single copy of electronic comments or two paper copies of any mailed comments to Leila G. Saldanha at *saldanhl@mail.nih.gov* or Department of Health and Human Services, c/o Office of Dietary Supplements, 6100 Executive Blvd., Rm 3B01, MSC 7517, Bethesda, MD 20892–7517.

FOR FURTHER INFORMATION CONTACT: Leila G. Saldanha, Department of Health and Human Services, 6100 Executive Blvd., Rm 3B01, MSC 7517, Bethesda, MD 20892–7517, Phone: 301–496–0168, Fax: 301–480–1845, e-mail: *saldanhl@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background: Foods provide numerous chemical constituents that may influence health and disease prevention, in addition to those usually characterized as essential nutrients. The physiological implications of these food components have been the subject of recent scientific inquiries and publications. Widespread scientific, governmental, and consumer attention to these components, referred to here as ''bioactive food components,'' has sparked an interest about how they should be defined and how best to evaluate their significance in promoting health and disease prevention.

Bioactive food components exist not only in commonly consumed foods but also as ingredients in fortified foods and dietary supplements. Bioactive food components may have multiple sites of action, may interact with one or more dietary constituents, and may act directly or indirectly to produce the functional outcome. Some examples of these components include lycopene, long-chain omega-3 fatty acids, epigallocatechin gallate (EGCG), isoflavones, sulphorophane, and resveratrol. Food sources of these components include, respectively, tomatoes, fatty fish, green tea, soybeans, broccoli, and red grapes, but other foods may be significant sources of bioactive food components.

An ad hoc Federal working group that includes representatives from the Departments of Health and Human Services (HHS), Defense, and Agriculture, and agencies within these departments such as the National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration, is interested in establishing a definition for ''bioactive food components'' as a first step toward developing approaches that might be used to assess their health effects. Currently, there is no generally accepted definition about what should be classified as a bioactive food component. Further, there are no generally accepted approaches for evaluating the health effects resulting from consuming these components. Establishing a definition for bioactive food components may help in guiding and encouraging future research with these components. An approach to assess the health effects of bioactive food components may need to take into account the complex nature of this category of components. In addition, it may provide science-based information to help guide public health policy on how Americans may choose diets that promote good health.

Written Comments: By this notice, ODPHP, on behalf of the ad hoc Federal working group, is soliciting submission of written comments on the following proposed definition of ''bioactive food components:'

Bioactive food components are constituents in foods or dietary supplements, other than those needed to meet basic human nutritional needs, that are responsible for changes in health status.

In making comments on the proposed definition, please provide the rationale for your comments. Comments are specifically requested on the following questions:

(1) What categories/classes of compounds should be considered as bioactive food components?

(2) What categories/classes of compounds should *not* be considered as bioactive food components? How should the definition be modified to reflect exclusion of these compounds?

(3) Should essential nutrients be included as bioactive food components?

(4) Should synthetically derived components used in fortified foods and dietary supplements be considered under this definition?

Written comments received in response to this notice will be reviewed by the ad hoc Federal working group and considered in refining the proposed definition of ''bioactive food components'' and in future plans involving the use of this definition.

(Authority: 42 U.S.C. 300u.)

Dated: September 10, 2004.

Cristina V. Beato,

Acting Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 04–20892 Filed 9–15–04; 8:45 am]

BILLING CODE 4150–32–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 04064 (Supplemental)]

ADAPT: Adopting and Demonstrating the Adaptation of Prevention Techniques Amendment

A notice announcing the availability of supplemental fiscal year (FY) 2004 funds for a cooperative agreement entitled, ''ADAPT: Adopting and Demonstrating the Adaptation of Prevention Techniques'' was published in the **Federal Register** Monday, August 23, 2004, volume 69, number 162, pages 51847–51851. The notice is amended as follows:

- On page 51849, column two, the Funding Restrictions section, please note funds provided by the ADAPT supplement can only be used for the adaptation of the intervention being implemented with the original PA 04064 funding. Adaptation activities include formative activities, monitoring and evaluation of the processes used to adapt the intervention, and evaluation of the adapted intervention and not for implementation of the intervention.
- On page 51847, column two, the Activities section, please note preference for ADAPT supplemental funding will no longer be given to Many Men, Many Voices. The following interventions will be equally considered for ADAPT supplemental funding:

1. Community Promise
2. Healthy Relationships
3. Holistic Harm Reduction
4. Many Men, Many Voices
5. Mpowerment
6. Partnership for Health
7. Popular Opinion Leader
8. Real AIDS Prevention Project
9. Safety Counts
10. SISTA
11. Street Smart
12. Teens Link to Care
13. VOICES/VOCES

- On page 51848, column one, Eligibility section, please note the sample size listed in letter *b* should be amended. The sample size should be similar to the original study. However, when this is not possible, the applicants who propose the largest sample sizes

may be given preference. A minimum sample size of 200 is desirable but not required.

Dated: September 10, 2004.

William P. Nichols,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04–20875 Filed 9–15–04; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0401]

Agency Information Collection Activities; Proposed Collection; Comment Request; Customer/Partner Service Surveys

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 voluntary customer satisfaction service surveys to implement Executive Order 12862.

DATES: Submit written or electronic comments on the collection of information by November 15, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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 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.

Customer/Partner Service Surveys (OMB Control Number 0910–0360)—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the agency. Executive Order 12862, entitled, ''Setting Customer Service Standard,'' directs Federal agencies that ''provide significant services directly to the public'' to ''survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.'' FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as the following: Food processors; cosmetic drug, biologic and medical device manufacturers; consumers; and health professionals. The request also covers ''partner'' (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness and accuracy of information, courtesy, and problem resolution in the context of individual programs.

FDA projects that approximately 15 customer/partner service surveys will be conducted per year, with a sample of between 50 and 6,000 customers, requiring an average of 18 minutes for review and completion for each survey. Some of these surveys will be repeats of earlier surveys, for purposes of monitoring customer/partner service and developing long-term data.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	Number of Respondents	Annual Frequency per Response	Hours per Response	Total Hours
Mail/telephone/fax/web-based	15,000	1	.30	4,500

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