related illnesses occurring in the United States.

There is no change in the frequency of reporting or projected reporting. Most respondents are epidemiologists or nurses in the local health department, but in some instances, infection control nurses or physicians might complete the form. The total cost per respondent is estimated at $11.00. This is primarily salary but also includes postage and telephone calls.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden of response (in hrs.)	Total burden (in hrs.)
Local health department staff	90	1	.33	30
Health care facility staff	45	1	.33	15
Physicians	15	1	.33	5
Total				50

Dated: September 1, 1999.

Nancy Cheal,

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

[FR Doc. 99–23282 Filed 9–7–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC) Meeting: Correction

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announced the following committee meeting in the **Federal Register** on August 23, 1999, Volume 64, Number 162, Page 45971.

Name: Clinical Laboratory Improvement Advisory Committee (CLIAC).

Times and Dates: 8:30 a.m.–5 p.m., September 22, 1999. 8:30 a.m.–3:30 p.m., September 23, 1999.

Correction: Please note, ''potential rulemaking for genetic testing'' should be added to the previously published agenda.

Contact Person for Additional Information: John C. Ridderhof, Dr.P.H., Division of Laboratory Systems, Public Health Practice Program Office, CDC, 4770 Buford Highway, NE, M/S G–25, Atlanta, Georgia 30341–3724, telephone 770/488–8076, FAX 770/488–8282.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for the both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 99–23382 Filed 9–3–99; 10:00 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H]

Food Labeling; Health Claims and Label Statements; Request for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting scientific data, research study results, and other related information on four substance-disease relationships in order to reevaluate the scientific evidence for these relationships. The agency is taking this action to comply with a recent court decision in which FDA was instructed to reconsider whether to authorize health claims for these relationships in dietary supplement labeling. The four health claims to be reconsidered are: ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' ''Consumption of fiber may reduce the risk of colorectal cancer,'' ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' The agency will use the data and information to determine, for each substance-disease relationship, if an appropriate scientific basis exists to support the issuance of a proposed rule to authorize a health claim for the relationship.

DATES: Written comments by November 22, 1999.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: The Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act), directed the Secretary of Health and Human Services, among other things, to evaluate the scientific evidence on 10 substance-disease relationships to determine their scientific validity as the basis for health claims in food labeling. For conventional foods, the 1990 amendments state that a health claim is permitted only if FDA determines that there is significant scientific agreement among qualified experts that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles (section 403(r)(3)(B)(i) of the act (21 U.S.C. 343(r)(3)(B))). While the 1990 amendments allowed FDA to consider a different scientific standard for health claims for dietary supplements (section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(5)(D))), FDA issued regulations in 21 CFR 101.14(c) in 1994 that applied the same standard as that used for health claims for conventional foods (59 FR 395, January 4, 1994).

FDA conducted rulemakings in which it reviewed the scientific evidence for all 10 substance-disease relationships. Although the agency issued regulations authorizing health claims for most of these relationships, it concluded that there was insufficient scientific agreement regarding the scientific validity of the four health claims listed in the **Summary** section of this document. Therefore, the agency issued regulations providing that these claims were not authorized. (See § 101.71(a), (c), (e) (21 CFR 101.79(c)(2)(i)(G)).

Several dietary supplement marketers and nonprofit organizations that had submitted comments during the health claims rulemakings filed suit in Federal district court on constitutional and statutory grounds seeking, among other things, authorization to make the following health claims for use in the labeling of dietary supplements: (1) ''Consumption of antioxidant vitamins may reduce the risk of certain kinds of cancer,'' (2) ''Consumption of fiber may reduce the risk of colorectal cancer,'' (3) ''Consumption of omega-3 fatty acids may reduce the risk of coronary heart disease,'' and (4) ''0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form.'' Their constitutional and statutory challenges were rejected in the district court; however, on appeal the district court decision was reversed, and FDA was instructed to reconsider the four health claims (*Pearson* v. *Shalala*, 164 F.3d 650 (D.C. Cir. 1999)).

As a first step in complying with the court's decision, FDA intends to reevaluate the scientific evidence for the four substance-disease claims listed above. The agency is now in the process of preparing scientific summaries on each of these four topics. To ensure that all relevant scientific evidence is considered in the rulemaking process and to allow timely development of these summaries, FDA is requesting that anyone who has or is aware of relevant scientific data, research study results, or information related to these four substance-disease relationships submit the materials to Dockets Management Branch (address above). Such information, if submitted to FDA, must be considered publicly available. If used in the agency's scientific review, information submitted to FDA will become part of the public record for the evaluation of these relationships.

The agency has established four dockets to compile information relating to each of the four topic areas; docket numbers are as specified in Table 1 below. FDA advises that the **Federal Register** documents listed in the footnotes to the table have been incorporated into each of the referenced dockets (Docket Nos. 91N–0101, 91N–0098, 91N–0103, and 91N–100H). FDA is requesting data and information other than the information contained or referred to in these **Federal Register** documents. As a guideline, therefore, the agency is requesting data and information from 1992 to the present for the four topic areas.

FDA is allowing 75 days for the submission of data. Individuals and organizations submitting information or data relating to a specific topic should submit two copies of the information to the Dockets Management Branch (address above) by November 22, 1999. Separate submissions should be made for each topic area, and each submission should be identified with the appropriate docket number given below. Submissions received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

TABLE 1

Topic	Docket No.
Antioxidant vitamins and cancer [1] and [2]	91N–0101
Fiber and colorectal cancer [3] and [4]	91N–0098
Omega-3 fatty acids and coronary heart disease [5] and [6]	91N–0103
Folic acid (dietary supplement vs. food form) and neural tube defects [7] and [8]	91N–100H

[1] ''Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60624 to 60651, November 27, 1991).

[2] ''Food Labeling: Health Claims and Label Statements; Antioxidant Vitamins and Cancer,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2622 to 2660, January 6, 1993).

[3] ''Food Labeling: Health Claims; Dietary Fiber and Cancer,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60566 to 60582, November 27, 1991).

[4] ''Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cancer,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2537 to 2551, January 6, 1993).

[5] ''Food Labeling: Health Claims and Label Statements; Omega-3 Fatty Acids and Coronary Heart Disease,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (56 FR 60663 to 60689, November 27, 1991).

[6] ''Food Labeling: Health Claims and Label Statements; Omega-3 Fatty Acids and Coronary Heart Disease,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (58 FR 2682 to 2738, January 6, 1993).

[7] ''Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects,'' Department of Health and Human Services, Food and Drug Administration, proposed rule, FEDERAL REGISTER (58 FR 53254 to 53295, October 14, 1993).

[8] ''Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects,'' Department of Health and Human Services, Food and Drug Administration, final rule, FEDERAL REGISTER (61 FR 8752 to 8781, March 5, 1996).

Dated: September 1, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–23337 Filed 9–7–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0433]

Draft Guidance for Industry on Average, Population, and Individual Approaches to Establishing Bioequivalence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Average, Population, and Individual Approaches to Establishing Bioequivalence.'' This draft guidance provides recommendations to sponsors and/or applicants intending to perform in vivo and in vitro bioequivalence (BE) studies based on comparisons of in vivo and in vitro