

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).

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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.

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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)).