

U. S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Food Labeling  
July, 1999

9843 '01 SEP 19 A7:32

## Health Claim Notification for Whole Grain Foods

Under the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA), a manufacturer may submit to FDA a notification of a health claim based on an authoritative statement from an appropriate federal agency or the National Academy of Sciences (NAS). If FDA does not act to prohibit or modify such a claim within 120 days of receipt of the notification, the claim may be used.

On March 10, 1999, General Mills, Inc. submitted to the agency a notification containing a prospective claim about the relationship of whole grain foods and heart disease and certain cancers. The notification cited the following statement from the Executive Summary of the NAS report, *Diet and Health: Implications for Reducing Chronic Disease Risk* (page 8), as an authoritative statement: "Diets high in plant foods--i.e., fruits, vegetables, legumes, and whole-grain cereals--are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach." For purposes of bearing the prospective claim, the notification defined "whole grain foods" as foods that contain 51 percent or more whole grain ingredient(s) by weight per reference amount customarily consumed (RACC). It proposed that compliance with this definition could be assessed by reference to the dietary fiber level of whole wheat, the predominant grain in the U.S. diet. Whole wheat contains 11 grams of dietary fiber per 100 grams; thus, the qualifying amount of dietary fiber required for a food to bear the prospective claim could be determined by the following formula:  $11 \text{ grams} \times 51\% \times \text{RACC}/100$ .

On March 12, 1999, FDA asked NAS for its comments on whether the statement cited in the notification met the requirements of section 303 of FDAMA. By letter on April 30, 1999, the Director of the Food and Nutrition Board (FNB) pointed out that in May 1997, the NRC Governing Board of NAS approved a policy statement regarding authoritative statements made by it or its subdivisions, the National Research Council (NRC) and the Institute of Medicine (IOM), noting that these "are limited to those that represent the consensus of a duly-appointed committee or views of a duly-appointed principal investigator so that they appear explicitly as findings, conclusions, or recommendations in a report that has completed the institutional report review process." The FNB Director also noted that the FNB and the NRC are not in a position routinely to review notifications to affirm the extent to which statements are authoritative under FDAMA. However, as previously indicated, the Executive Summary of *Diet and Health*, which integrates all the evidence reviewed in the total report, provides the report's findings, general conclusions and recommendations based on consensus of the Committee on Diet and Health.

FDA considered the information provided by NAS and conducted a further review of the statement in its context and in comparison to the existing authorized health claims for fruits, vegetables and grain.

products including the claim related to coronary heart disease that relies on the presence of a level of soluble fiber as a marker. FDA's decision not to prohibit or modify the claim means that as of July 8, 1999, the manufacturers may use the following claim on the label and in labeling of any product that meets the eligibility criteria described in the notification: "Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers."

The notification and additional materials regarding the claim are publicly available from the FDA Dockets Management Branch (Docket No. 99P-2209). Persons interested in these documents may view them at the Dockets Management Branch from 9 am to 4 pm, Monday through Friday, or access them on the daily Dockets web site at <http://www.fda.gov/ohrms/dockets/dailys/070899/070899.htm>. Dockets Management Branch may be contacted at 301-827-6860.

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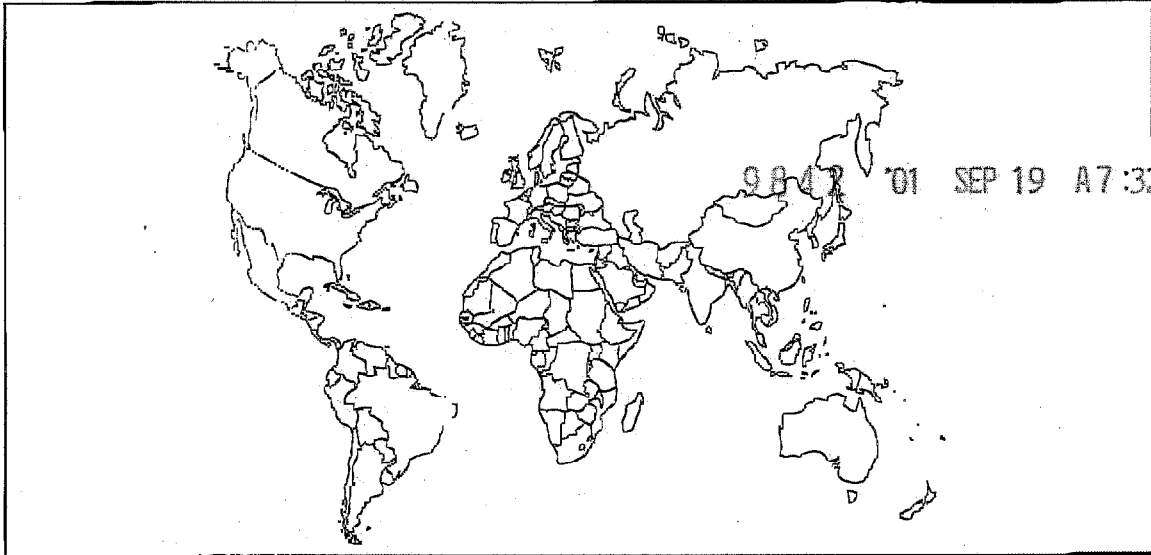
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SUBJECT: FDA Docket # 99P-2209

MESSAGE: This covers 99P-2209. As you know  
this is not a citizen petition. it is a notification  
(a) re health claim.