

**CSPI** CENTER  
FOR SCIENCE  
IN THE  
PUBLIC INTEREST

Publisher of **Nutrition Action Healthletter**

June 26, 2000

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

7295 '00 JUN 27 A940

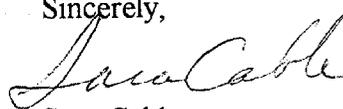
**Re: Citizen Petition Requesting Enforcement Action to Prohibit Kellogg from  
Making an Unapproved Health Claim.**

To the Clerk:

Please find enclosed the original and four copies of the Citizen Petition from the Center for Science in the Public Interest in the above referenced matter.

Please call (202) 332-9110, ext. 362 with any questions. Thank you.

Sincerely,



Sara Cable  
Legal Assistant

00P-1369

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Citizen Petition Requesting Enforcement )  
Action to Prohibit Kellogg from Making )  
an Unapproved Health Claim )  
\_\_\_\_\_ )

Docket No. \_\_\_\_\_

7 29 6 '00 JUN 27 19:40

Submitted by the

Center for Science in the Public Interest

June 26, 2000

Michael F. Jacobson, Ph.D.  
Executive Director  
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Suite 300  
Washington, D.C. 20009-5728  
202-332-9110

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Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
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12420 Parklawn Drive  
Rockville, MD 20857

### **Citizen Petition**

The undersigned submits this petition under Sections 403(a) and 403(r) of the Federal Food, Drug and Cosmetic Act (FDCA) to request that the Commissioner of Food and Drugs take prompt enforcement action against the Kellogg Company (Kellogg).

#### **I. Action Requested**

The Center for Science in the Public Interest (CSPI)<sup>1</sup> requests that the Food and Drug Administration (FDA) order Kellogg to remove the following claim from its cereals: "Adequate intakes of folic acid, vitamins B6 and B12 may promote a healthy cardiovascular system." The claim is an unapproved health claim and any products on which it appears are misbranded.

#### **II. Statement of Grounds**

On April 4, 2000, Kellogg announced that it will be the "nation's first leading food manufacturer to communicate on many of its adult targeted cereals that 'adequate intakes of folic acid, vitamins B6 and B12 may promote a healthy cardiovascular system.'"<sup>2</sup> Kellogg stated that it

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<sup>1</sup> CSPI is a nonprofit organization based in Washington, D.C. that is supported by over 800,000 members who subscribe to its *Nutrition Action Healthletter*. CSPI has been working to improve the public's health through better nutrition and safer food since 1971.

<sup>2</sup> Kellogg Press Release [hereinafter, Press Release], *Using new FDA regulations, Kellogg takes the lead in promoting heart-health benefits of folic acid*, April 5, 2000. The Press Release

is “pleased to launch the first major application of the Food and Drug Administration’s new regulations concerning structure/function claims on packaged foods.”<sup>3</sup> The FDA, however, has issued no such regulations and Kellogg is making a “health claim” that should have been pre-approved by the Agency following a notice and comment rulemaking proceeding.

Kellogg presumably did not seek such approval because on November 30, 1999 the FDA specifically denied a petition for a similar health claim. The Agency stated that it could not conclude that “based on the totality of publicly available scientific evidence, there is significant scientific agreement among experts qualified by training and experience to evaluate such evidence that a relationship between folic acid, vitamin B6, and vitamin B12 dietary supplements and risk of vascular disease is supported by the available evidence.”<sup>4</sup> Previously, the FDA had also rejected an attempt by Weider Nutrition International to gain approval of a similar claim pursuant to the “authoritative statement” provisions of the Food and Drug Administration Modernization Act (FDAMA).<sup>5</sup>

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lists the cereals “specially formulated for the structure/function claim” as: Special K, Special K Plus, Product 19, Smart Start, Complete Wheat Bran Flakes, Complete Oat Bran Flakes, Crispex, All-Bran, All-Bran Extra Fiber, All-Bran Bran Buds, Just Right, Healthy Choice Low Fat Granola, Healthy Choice Low Fat Granola with Raisins, and Healthy Choice Mueslix. (Attachment A.)

<sup>3</sup> Kellogg’s reliance on the Jan. 6, 2000 final regulation on structure/function claims is disingenuous. As the FDA stated in the Preamble to the rule, “This rule applies to claims for dietary supplements only.” FDA, Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body. 65 Fed. Reg. 999, 1034 (Jan. 6, 2000).

<sup>4</sup> Letter from Elizabeth Yetley, Director, Office of Special Nutritionals, FDA to Jonathan Emord, attorney for Julian Whitaker, M.D., Durk Pearson and Sandy Shaw, American Preventive Medical Association, and Pure Encapsulations, Inc., Nov. 30, 1999.

<sup>5</sup> 63 Fed. Reg. 34,097 (June 22, 1998). The FDA prohibited the proposed claim on the grounds that it was not supported by an authoritative statement.

Although there is promising evidence that appropriate levels of folic acid and vitamins B6 and B12 can reduce the risk of heart disease, the level of support for this conclusion has not yet reached the level of “significant scientific agreement” as required by the Nutrition Labeling and Education Act (NLEA). Kellogg’s backdoor attempt to make an implied health claim that is not approved by the FDA threatens to undermine the regulatory framework established by the NLEA. Allowing such claims -- particularly ones that have been disapproved by the FDA -- to masquerade as structure/function claims jeopardizes the viability of the health claim provisions of the FDCA that protect consumers from false and misleading labels.<sup>6</sup>

**A. The Products are Misbranded Because Kellogg’s Label Statements are Implied Health Claims that Require Agency Approval**

Kellogg’s claim constitutes an implied health claim under the criteria set forth in the implementing regulations to the NLEA. Health claims include any claim that expressly, *or by implication*,<sup>7</sup> characterizes the relationship of any substance to a disease or health-related condition.<sup>8</sup> No such claim may be made in the labeling of a food unless the claim is specifically authorized in the regulations and the claim conforms to the requirements in such regulations.<sup>9</sup>

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<sup>6</sup> It also sends a misleading message to the food industry that structure/function claims are subject to lower substantiation requirements when this should not be the case. Dr. Christine Lewis, Director of FDA’s Office of Nutritional Products, Labeling and Dietary Supplements, stated that the “starting point” for the debate is to apply the “significant scientific agreement” standard for both health claims and structure/function claims. Her statement was made at the April 26, 2000 Symposium on Structure/Function Claims for Foods sponsored by the National Academies Institute of Medicine, Food and Nutrition Board.

<sup>7</sup> The Agency defines implied health claims as “statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.” 21 C.F.R. § 101.14(a)(1).

<sup>8</sup> *Id.*

<sup>9</sup> 21 C.F.R. § 101.14(e).

In explaining how it evaluates implied health claims, the FDA made two key points. The first point is that:

Labeling claims need to be considered in their entirety and *in context* to determine whether the elements of a health claim are present. FDA has therefore revised the definition of an implied health claim. . . to clarify that the claim will be evaluated within the context of the total labeling to determine if an implied health claim has been made.<sup>10</sup>

The FDA's second point is that "the focus of its determination as to whether a claim is an implied claim should be on what the claim is saying." The FDA considers both manufacturers' *intent* and consumer perception to determine what is actually being said.<sup>11</sup>

The claim "heart healthy," for example, has been explicitly recognized by the Agency as an implied health claim. As the FDA explained: "[l]abeling that links a specific food to a statement such as 'Heart Healthy' contains both the substance element (reference to a specific food) and the disease-condition element (implied reduction in risk of heart disease) of a health claim."<sup>12</sup>

Under this principle, Kellogg's claim that "adequate intakes of folic acid, vitamins B6 and B12 may promote a healthy cardiovascular system" constitutes an implied "heart-healthy" claim. The slight difference in wording between Kellogg's detailed "heart-healthy" claim and the more succinct claim discussed by the Agency is insufficient to justify disparate treatment of each claim. This view is particularly appropriate in this case because Kellogg's own press release states that: "[t]he Kellogg's cereals now fortified with 100 percent of the daily values of folic acid, vitamins B6 and B12, provide consumers with a delicious way to meet dietary recommendations for these

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<sup>10</sup> 58 Fed. Reg. 2,478, 2,483 (Jan. 6, 1993) (emphasis added).

<sup>11</sup> *Id.*

<sup>12</sup> U.S. Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Questions and Answers, Volume II: A Guide for Restaurants and Other Retail Establishments 22 (1995).

important *heart-healthy* nutrients.”<sup>13</sup> And its website states, “You can enjoy the benefits of a more heart-healthy diet now . . .”<sup>14</sup>

In this case, an evaluation of the context in which the claim appears demonstrates that the claim is indeed an implied health claim.<sup>15</sup> Kellogg’s new line of cereals can be readily identified by the red star with a blue banner on the front panel. The banner states: “Good news for your heart -- 100% Daily Value Folic Acid, B6, B12.” Kellogg’s website, the address of which appears on its cereals, describes the link between homocysteine levels and heart disease and how the nutrients in its cereal work together to maintain “healthy blood levels of homocysteine.”<sup>16</sup>

Thus, when the label statement is read in context, it is clear that Kellogg is making an implied health claim. Because the FDA has not approved such a claim, the cereals bearing the statement are misbranded.

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<sup>13</sup> Press Release, *supra* note 2 (emphasis added).

<sup>14</sup> April 6, 2000 website, <[http://www.kelloggs.com/nutrition/heart\\_disease/heart\\_what.html](http://www.kelloggs.com/nutrition/heart_disease/heart_what.html)> [hereinafter, Kellogg website] (Attachment B); revised as of June 1, 2000, <[http://www.kelloggs.com/nutrition/heart\\_disease/index.html](http://www.kelloggs.com/nutrition/heart_disease/index.html)> [hereinafter, Kellogg website revised] (Attachment C). The quoted language is identical on both the original and revised websites.

<sup>15</sup> In its proposed rule for regulations on structure/function claims made for dietary supplements, the FDA stated that: “[a] statement that by itself would be considered an acceptable structure/function claim could become a disease claim if, in context, an effect on disease were expressed or implied.” The agency stated that even though a claim that a substance helps maintain normal function would not ordinarily be a disease claim, it could become one if the *context* did suggest treatment or prevention of a disease. 63 Fed. Reg. 23,624, 23,626 (1998). FDA’s final rule on structure/function claims upholds this principle. 65 Fed. Reg. 999 (Jan. 6, 2000). The final regulation states: “In determining whether a statement is a disease claim. . . it will consider the context in which the claim is presented.” *Id.* at 1050, to be codified at 21 C.F.R. § 101.93 (g)(2).

<sup>16</sup> Kellogg website, *supra* note 14. The revised website retains the language quoted from the earlier cite.

## **B. The Products are Misbranded Because Kellogg's Intent is to Make an Impermissible Disease Claim**

Under the definition of a drug found in the FDCA, "intent" is key to determining whether a product is in fact a drug.<sup>17</sup> "It is well established that the "intended use" of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source . . ."<sup>18</sup> As explained in *Hanson v. Schuster*:

Countless court decisions emphasize that it is the *intended use* of an article which determines whether or not it is a "drug," and that even the most commonly ingested foods and liquids are 'drugs' within the meaning of the Act if the intended use of such articles when distributed in interstate commerce falls within the definition of § 321(g)(1). . . .<sup>19</sup>

Although Kellogg asserts that its label statement is worded as a structure/function claim, it is evident that the product is being promoted for disease prevention purposes. The April 4, 2000 press release discusses how folic acid, B6 and B12 prevent homocysteine levels from being elevated. Elevated levels of homocysteine, Kellogg explains, "may *damage* arterial walls." (Emphasis added). On its website, which is listed in both the press release and on its cereal packages, Kellogg plainly states that "people with elevated levels of homocysteine in their blood have a higher risk for heart and blood vessel damage related to heart disease."<sup>20</sup> "Damage to

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<sup>17</sup> FDCA § 201(g), 21 U.S.C. § 321(g). "The term 'drug' means: articles *intended* for use in the diagnosis, cure, mitigation, treatment or prevention of disease. . . ." *Id.* (Emphasis added).

<sup>18</sup> *Hanson and Shuster v. U.S.*, 417 F. Supp. 30, 35 (D. Minn.), *aff'd* 540 F.2d 947 (8th Cir. 1976).

<sup>19</sup> *Id.* at 34-35.

<sup>20</sup> Kellogg website, *supra* note 14. A revised website weakens the definitiveness of the claim by linking it to an "*association* between elevated homocysteine levels and an increased risk of heart and blood vessel damage related to heart disease." (emphasis added) Nevertheless, Kellogg's intent to make a disease claim is still apparent. Kellogg website revised, *supra* note 14. Advertising can be taken into account by the FDA in determining the manufacturer's intent to make a drug claim. *Hanson, supra*, note 18 at 35. "Intended use is also established by the claims on . . . Internet web sites." Letter from James A. Rahto, Director, Minneapolis District, FDA, to Terrence J. Lemerond, President, Enzymatic Therapy, Inc. (May 5, 2000).

arterial walls” and “blood vessel damage” fall within the definition of “disease” that was adopted by FDA in connection with the health claim regulations<sup>21</sup> and reaffirmed as the operative definition in the structure/function rule relied on by Kellogg.<sup>22</sup> That definition states that:

“‘disease’ is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g. cardiovascular disease).”<sup>23</sup>

Thus it is evident that Kellogg’s products are misbranded. Kellogg clearly intends to make a disease claim and should be required to follow the appropriate procedures to obtain approval of a health claim.

### **C. The Kellogg Claim is Misleading Because it is Likely to be Confused with Approved Health Claims**

In situations in which a structure/function claim is made with respect to a nutrient or disease that is also the subject of an approved health claim, there is a likelihood of consumer confusion and deception.

The claim being made by Kellogg may easily be confused with claims that have already been approved that relate to the reduction of coronary heart disease. These include claims regarding dietary saturated fat and cholesterol,<sup>24</sup> fruits, vegetables, and grain products that contain fiber,<sup>25</sup> and fiber from whole oats and psyllium.<sup>26</sup> In addition, the FDA has approved a claim

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<sup>21</sup> 21 C.F.R. § 101.14(a)(5).

<sup>22</sup> Food and Drug Administration Regulation on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body; Final Rule, 65 Fed. Reg. 999, 1009-1010 (Jan. 6, 2000).

<sup>23</sup> 65 Fed. Reg. at 1050, to be codified at 21 C.F.R. § 101.93(g).

<sup>24</sup> 21 C.F.R. § 101.75.

<sup>25</sup> 21 C.F.R. § 101.77.

<sup>26</sup> 21 C.F.R. § 101.81.

linking the consumption of folate to a reduction in the risk of neural tube birth defects.<sup>27</sup> It is possible that many consumers will confuse such approved messages with Kellogg's unapproved claim. The use of the unapproved claim is, therefore, misleading under section 403(a) of the Act, 21 U.S.C. § 343(a), and should be prohibited.

### **III. Conclusion**

Given Kellogg's attempts to circumvent the law, we believe that the FDA should take prompt enforcement action against the company. It is incumbent upon the FDA to maintain the integrity of the NLEA by prohibiting unapproved health claims from masquerading as structure/function claims.

### **IV. Environmental Impact**

This petition is subject to a categorical exclusion under 21 C.F.R. § 25.30(b) and, therefore, CSPI is not required to prepare an environmental assessment.

### **V. Economic Impact**

No statement of economic impact is required at this time.

### **VI. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes

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<sup>27</sup> 21 C.F.R. § 101.79.

representative data and information known to the petitioner which are unfavorable to this petition.

Respectfully submitted,

Bruce Silverglade  
Director of Legal Affairs

A handwritten signature in cursive script, appearing to read "Ilene R. Heller".

Ilene Ringel Heller  
Senior Staff Attorney

Attachments

Using new FDA regulations, Kellogg takes the lead  
in promoting heart-health benefits of folic acid

WASHINGTON, DC April 4, 2000 -- Kellogg Company announced today that it will be the nation's first leading food manufacturer to communicate on many of its adult targeted cereals that "adequate intakes of folic acid, vitamins B6 and B12 may promote a healthy cardiovascular system."

"We are pleased to launch the first major application of the Food and Drug Administration's new regulations concerning structure/function claims on packaged foods," said Guy H. Johnson, Ph.D., vice president, nutrition, Kellogg USA.

The FDA regulations, issued in January, differentiate structure-function claims from health claims. Under the new regulations, structure-function claims, "describe the effect of a nutrient or dietary ingredient on the normal structure or function of the body."

The claim is based on a comprehensive assessment of the scientific evidence by experts in a variety of nutrition and public health sectors, including an international panel of leading vascular researchers. "Thirty years of accumulated research suggest that adequate intakes of folic acid, vitamin B6 and B12 may help promote a healthy heart," said Eric Rimm, Ph.D., associate professor of epidemiology, Harvard School of Public Health.

Consumers can identify the newly fortified Kellogg's(R) cereals by looking on the front panel of the box for a red star with a blue banner that says, "Good News for Your Heart -- 100% Daily Value Folic Acid, B6, B12" or by reading the nutrition facts panel. Additional information on the three B-vitamin's link to heart health will appear prominently on select cereal boxes.

The Kellogg's® cereals specially formulated for the structure-function claim are: Special K®, Special K Plus®, Product 19®, Smart Start®, Complete® Wheat Bran Flakes, Complete® Oat Bran Flakes, Crispix®, All-Bran®, All-Bran® Extra Fiber, All-Bran® Bran Buds®, Just Right®, Healthy Choice® Low Fat Granola, Healthy Choice® Low Fat Granola with Raisins and Healthy Choice® Mueslix®.

"Kellogg Company's decision to put a structure/function claim on these cereals demonstrates the leadership a major food company can provide in communicating nutrition science to the public," said Maureen Storey, Ph.D., associate director, Georgetown Center for Food and Nutrition Policy. "Kellogg evaluated the research with the panel, examined other reviews of the research, and translated public policy into a heart healthy message for consumers." The center, with support from Kellogg Company, was responsible for assembling the scientific panel that reviewed the research.

"Kellogg Company has a long-standing tradition of applying the latest research to provide consumers with foods that meet their demand for health benefits as well as taste," said Johnson, Kellogg USA. "In fact, Kellogg pioneered modern health claims when it printed the National Cancer Institute's dietary recommendations on its high-fiber All-Bran® cereal boxes in 1984."

One way folic acid and vitamins B6 and B12 may help promote cardiovascular health is by keeping a normal level of homocysteine in the blood. Homocysteine is an amino acid made in the body, and our bodies use folic acid and vitamins B6 and B12 to further convert homocysteine to other compounds. When people don't get enough of these B vitamins, homocysteine accumulates in the blood and may damage arterial walls.

According to the most recent USDA Continuing Survey of Food Intake by Individuals (CSFII), an estimated 49 percent of American adults do not consume the Recommended Dietary Allowance (RDA) of folic acid from foods. Additionally, nearly 40 percent do not consume the RDA of vitamins B6 and 28 percent have sub-optimal intakes of B12. The Kellogg's® cereals now fortified with 100 percent of the daily values of folic acid, vitamins B6 and B12, provide consumers with a delicious way to meet dietary recommendations for these important heart-healthy nutrients.

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With sales of nearly \$7 billion, Kellogg Company is the world's leading producer of ready-to-eat cereal and a leading producer of convenience foods, including toaster pastries, cereal bars, frozen waffles, and veggie foods. The company's brands include Kellogg's®, Special K®, Rice Krispies®, Eggo®, Pop-Tarts®, Nutri-Grain®, and Morningstar Farms®. Kellogg icons such as Tony the Tiger® and Snap!® Crackle!® Pop!® are among the most recognized characters in advertising. Kellogg products are manufactured in 20 countries and marketed in more than 160 countries around the world. For more information, visit the Kellogg Web site at <http://www.kelloggs.com>. TM, ©Kellogg Company © 2000 Kellogg Company \*Healthy Choice® is a registered trademark of ConAgra, Inc. used under license

Attachment B: Kellogg's Website

Heart Disease Facts

[Role of B Vitamins in Heart Disease](#)

[What is Homocysteine?](#)

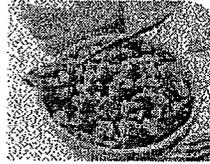
[How Do B Vitamins Help?](#)

[How Much Folic Acid Do I Need?](#)

[Where Can I Get Folic Acid?](#)

[Sources of Folate](#)

### What is Homocysteine?



Everyone's blood has homocysteine, which is a substance that comes from breaking down the proteins we eat. Studies have found that people with elevated levels of homocysteine in their blood have a higher risk for heart and blood vessel damage related to heart disease.

Many studies show that folic acid, vitamin B6 and vitamin B12 work together to maintain healthy blood levels of homocysteine. But when these vitamins are in short supply in the body, excess homocysteine accumulates.

You can enjoy the benefits of a more heart-healthy diet now, by taking steps to ensure you're meeting the recommended levels for these nutrients. You've always counted on **Kellogg's®** cereals for a great start to your morning. Now, that start may be even healthier for your heart.

### ► Nutrition Info

- [Breakfast](#)
- [Calcium](#)
- [Dietary Fiber](#)
- [Folate](#)
- [Heart Disease](#)
- [Pregnancy](#)
- [Kids and Fiber](#)
- [Whole Grain](#)

### ► Nutrition Camp

- [Fun Center](#)
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- **Heart Disease Facts**
- [Role of B Vitamins in Heart Disease](#)
- [What is Homocysteine?](#)
- [How Do B Vitamins Help?](#)
- [How Much Folic Acid Do I Need?](#)
- [Where Can I Get Folic Acid?](#)
- [Sources of Folate](#)

# Living A Healthy Life



**Heart Disease Facts:**

It's the #1 killer in the United States.  
[More info...](#)

You can enjoy the benefits of a more heart-healthy diet now.  
[More info...](#)

Vitamin B6 is essential for a healthy nervous system and healthy blood.  
[More info...](#)

## ► Nutrition Info

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- [Heart Disease](#)
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## ► Nutrition Camp

FOR KIDS

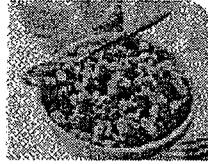
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- Heart Disease Facts
- Role of B Vitamins in Heart Disease
- What is Homocysteine?**
- How Do B Vitamins Help?
- How Much Folic Acid Do I Need?
- Where Can I Get Folic Acid?
- Sources of Folate



### What is Homocysteine?

Everyone's blood has homocysteine, which is a substance that comes from breaking down the proteins we eat. Studies have shown an association between elevated levels of homocysteine in blood and a higher risk for heart and blood vessel damage related to heart disease.

Many studies show that folic acid, vitamin B6 and vitamin B12 work together to maintain healthy blood levels of homocysteine. But when these vitamins are in short supply in the body, excess homocysteine accumulates.

You can enjoy the benefits of a more heart-healthy diet now, by taking steps to ensure you're meeting the recommended levels for these nutrients. You've always counted on Kellogg's® cereals for a great start to your morning. Now, that start may be even healthier for your heart.

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