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July 6, 1999

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**VIA FACSIMILE AND REGULAR MAIL**

Ms. Christine Lewis (IFS-451)  
Deputy Director  
Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, DC 20204

Re: *General Mills, Inc.; Whole Grain Foods Authoritative Statement Claim Notification*

Dear Ms. Lewis:

On behalf of General Mills, Inc. ("General Mills"), I make the following supplements to the "Whole Grain Foods Authoritative Statement Claim Notification," submitted by Patton Boggs LLP, on behalf of General Mills, on March 10, 1999. These amendments are made without prejudicing the 120-day notification period set forth in section 303 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA").<sup>1</sup>

**1. Difference from Existing Claims**

The notification is amended to include the following statement on page 27, immediately following the last paragraph of section VII, "Consistency with Currently Authorized Health Claims," and preceding section VIII, "Conclusion":

"The whole grain foods claim is not equivalent to any authorized health claims, including those for fiber. The whole grain foods claim refers to 'diets rich in whole grain foods and other plant foods,' as opposed to fiber-containing foods. Rather than fiber being a food component referred to in the claim as necessary for the beneficial relationship, the whole

<sup>1</sup> Pub. L. No. 105-115 (November, 21, 1997).

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grain claim recognizes the explicit wording, and intended meaning, of the authoritative statement: whole grain foods themselves have a beneficial effect that cannot be attributed to fiber, or any other single component of the foods. Furthermore, because diets that satisfy the whole grain claim, do not necessarily satisfy the fiber claims, and vice versa, the claims are clearly mutually exclusive. Thus, the proposed whole grain foods claim satisfies FDAMA's requirements because it is appropriately based on an authoritative statement, and is not equivalent to an already-authorized health claim."

## 2. Model Claim

The model claim set forth on page 10 of the notification is amended to read:

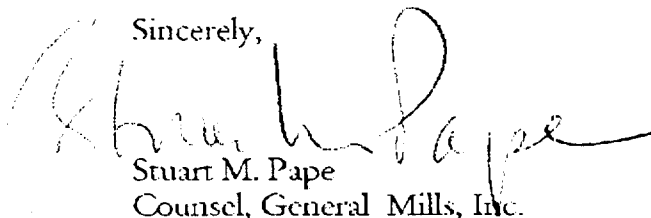
*Diets rich in whole grain foods and other plant foods and low in total fat, saturated fat, and cholesterol, may help reduce the risk of heart disease and certain cancers.<sup>2</sup>*

The amended model claim includes the concept that a diet should be low in saturated fat and cholesterol (as well as low in total fat and rich in whole grain foods and other plant foods) in order to have the potentially beneficial effects on heart disease risk.

## 3. Confidentiality

General Mills does not object to the Food and Drug Administration making public the March 10, 1999, notification, and this letter, on July 8, 1999, the day the 120-day notification period set forth in FDAMA expires and the claim takes effect.

Sincerely,



Stuart M. Pape  
Counsel, General Mills, Inc.

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<sup>2</sup> The claim would not need to refer to "saturated fat and cholesterol" if the disease endpoint in the claim were only "certain cancers."