

Upsher-Smith Laboratories, Inc. Innovative Pharmaceuticals Since 1919

November 29, 2000

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CERTIFIED MAIL/RETURN RECEIPT REQUESTED

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

Dear Sir/Madam,

Pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act, this is to notify you that we will be making the following statement of nutritional support in the product and promotional labeling and advertising for our dietary supplement product FolgardTM (Folic Acid, Vitamin B₆, Vitamin B₁₂ Combination):

• Healthy Heart Formula

Should you have any questions or comments, please contact me at (763) 449-7253.

Sincerely,

UPSHER-SMITH LABORATORIES, INC.

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Kimberly Oakins Regulatory Affairs Associate

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UPSHER-SMITH

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