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Upsher-Smith Laboratories, Inc. 1887 '99 APR 20 P2:04

Innovative Pharmaceuticals Since 1919

March 31, 1999

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4/5/99

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 21 CFR 101.93, this is to notify you that Upsher-Smith Laboratories, Inc., located at 14905 23rd Avenue North, Minneapolis, MN 55447, will be making the following statement of nutritional support in the product and promotional labeling and advertising for the dietary supplement Provol™, *Pygeum africanum*, 50 mg.

- Helps maintain normal urine flow

Should you have any questions or comments, please contact me at (612) 449-7315.

Sincerely,

UPSHER-SMITH LABORATORIES, INC.

Mark B. Halvorsen, Pharm.D.
Manager, Clinical and Regulatory Affairs

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