



6776 '99 DEC -6 P1:44

December 1, 1999

Jonathan W. Emord, Esq.
Emord and Associates, P.C.
1050 Seventeenth Street, NW
Suite 600
Washington, DC 20036

RE: Petition for Health Claim: Saw Palmetto and Benign Prostatic Hyperplasia (Docket Number 99P-3030)

Dear Mr. Emord:

This responds to your health claim petition dated May 25, 1999, submitted to the Food and Drug Administration (FDA) on behalf of Julian Whitaker, M.D., Durk Pearson and Sandy Shaw, American Preventive Medical Association, and Pure Encapsulations, Inc., requesting that the agency authorize a health claim on the relationship between dietary supplements of saw palmetto extract (specifically the *n*-hexane lipidosterolic extract of the pulp and seed of the dwarf American palm, *Serona repens*) and benign prostatic hyperplasia. Your petition was filed for comprehensive review on September 1, 1999, in accord with the procedures in 21 CFR § 101.70(j)(2). Ninety days have passed since the petition was filed and FDA has not taken action to deny the petition or to publish a proposed regulation to provide for the requested use of the health claim; thus, the petition is deemed to be denied under 21 U.S.C. § 343(r)(4)(A)(i) and 21 CFR § 101.70(j)(3)(iii).

FDA has allowed your petition to be denied by operation of law because the agency has been unable to resolve an important and novel issue that the petition raises. All previous health claim petitions that met the eligibility requirements in 21 CFR § 101.14(b) have addressed reduction of the risk of a disease or health-related condition. Because your petition goes beyond risk reduction to claim an effect on an existing disease, the agency has had to consider seriously whether health claims for foods (including dietary supplements) may encompass this type of claim or whether such a claim is appropriate only on a product that has been shown to meet the safety and efficacy requirements for drugs. The agency has been unable to reach a decision on your petition within the time provided by statute and regulation, and has decided to seek public input on the important question it raises. We will continue to work diligently to resolve this issue and, when a resolution is achieved, the agency will, on its own initiative, reconsider your health claim petition.

We will communicate with you shortly to advise you further regarding the procedure and process that we will use to make our decision.

Sincerely,

Elizabeth A. Yetley, Ph.D.
Director
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

99P-3030

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