



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

MAY 20 2004

Lars Pellas
VP, Corporate Development
Hormos Medical Corporation
PharmaCity
Itäinen Pitkätatu 4 B
20520 Turku
FINLAND

Dear Mr. Pellas:

This is to inform you that the notification, dated March 3, 2004, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on March 8, 2004. Your notification concerns the substance called 7-hydroxymatairesinol (HMR), that you intend to market as a new dietary ingredient.

You describe HMR as a substance extracted and purified from the Norway spruce tree (*Picea abies*, (L.) H. Karst.b)) wood chips and further processed as hydroxymatairesinol potassium acetate complex (HMR-potassium acetate complex). The dosage form will be oral capsules containing up to 50 milligrams (mg) HMR corresponding to approximately 72 mg of HMR potassium acetate complex. The suggested conditions of use are one capsule per day for a recommended maximum daily consumption of 50 mg HMR/day or approximately 1 mg/kilogram (kg) body weight/day for a 50 kg person. You also state that consumption of the HMR-potassium acetate complex is recommended for the use of adults only.

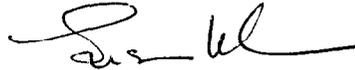
In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, you must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing 7-hydroxymatairesinol (HMR) if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of March 8, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

Should you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Susan J. Walker', written in a cursive style.

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition