



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

**MAY 24 2006**

Paul D. Rubin, Esq.  
Patton Boggs LLP  
2550 M St., NW  
Washington, D.C. 20037

Dear Mr. Rubin:

This is to inform you that the notification, dated December 23, 2005, that you submitted on behalf of your client, Stragen Pharma SA, 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 December 27, 2005. Additional information, dated February 6, 2005, was also received by FDA. Your notification concerns the substance that you identify as "Diosmin 95 Complex" that you intend to market as a new dietary ingredient in a dietary supplement product.

According to your notification, you intend to market a 720 mg tablet containing 600 mg of "Diosmin 95 Complex" as well as other non-dietary ingredients such as binders. Your notification also states that "the recommended duration of use is 1 dose per day for a maximum recommended duration of 3 months." Your notification states that "Stragen's Diosmin 95 Complex is not recommended for use by children or pregnant or nursing women and will be so labeled."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

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, your client must not introduce or

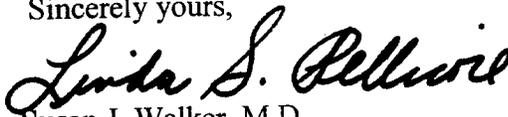
deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

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 your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

This letter supersedes the letter dated March 10, 2006.

If you have any further questions concerning this matter, please contact Linda S. Pellicore, Ph.D., at (301) 436-2375.

Sincerely yours,



*for* 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