



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

Mr. Michael G. Jeffers
JML Marketing, Inc.
700 North Walnut Street
Bloomington, Indiana 47408

OCT 13 2006

Dear Mr. Jeffers:

This is to inform you that the notification, dated July 25, 2006, that 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 August 1, 2006. Your notification concerned the substance that you called "EstroG-100™" that you identify as a new dietary ingredient. According to your notification, "EstroG-100™" is a combination of three botanical extracts derived, respectively, from the roots of *Angelica gigas* Nakai, from *Cynanchum wilfordii* (Maximowicz) J. D. Hooker, and from *Phlomis umbrosa* Turcz.

According to your notification, your ingredient will be sold "in dosage rates of 125 mg, three times per day..." in capsules containing the ingredient combined with unnamed excipients.

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 21 U.S.C. 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.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that "EstroG-100™" will reasonably be expected to be safe.

FDA was unable to establish the identity of your ingredient, "EstroG-100™". For example, there is contradictory information in your notification concerning whether the stems, leaves or roots of *Cynanchum wilfordii* will be the source of the extract used to make "EstroG-100™". The part of *Phlomis umbrosa* to be used to make "EstroG-100™" is similarly unclear. In

addition, the amount of the botanical extracts and identity of additional ingredients of "EstroG-100™" are unclear. According to your notification, "[t]he name 'Estromon' was used inter-changeably as the clinical trail code name during the research phase of EstroG-100." However, while Exhibit MSE describes "EstroG-100™" as containing equal parts (33.33%) of each of three botanical extracts, Exhibit FF describes "Estromon" as containing unequal portions of the three botanical extracts. Exhibit FF also includes a list of vitamins, minerals and other substances that do not appear to be excipients as ingredients in "Estromon". The presence of these additional dietary ingredients appears inconsistent with the statements in your notification that "The finished COMMERCIAL form (capsules) includes the two stated plant root extract and the root extract Descurinol™ combined with miscellaneous excipients." Because the identity of "EstroG-100™" is unclear, it is unclear how your ingredient is qualitatively and quantitatively similar to the substances that were used in the information submitted to demonstrate the safety of your ingredient or how that information can be used to establish the safety of "EstroG-100™" under the conditions of use suggested or recommended on the label of your dietary supplement product.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "EstroG-100™", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of August 1, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch 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.

If you have any questions concerning this matter please contact Theresa Prigmore at (301) 436-1446.

Sincerely yours,



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