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Jan. 18, 2000

Commissioner of Food and Drugs  
& Docket Managements Office  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Md. 20857

Re: Docket No. 98N-0044

Dear Commissioner Henney:

The Food and Drug Administration (FDA) recently issued a final rule on dietary supplements and structure and function claims. 65 Fed. Reg. 999 (Jan. 6, 2000). I had commented on the proposed rule, and some of my comments were accepted and some were not. I am still reviewing the rule and my aim in writing does not relate to making any overall comments on the rule.

My concern, instead, relates to the agency's position on a particular claim, that being that supplements can claim to be for "ordinary morning sickness associated with pregnancy." I agree with the agency's position that protection of health and safety is, and should be, one of the major purposes of the rule. Congress's reason for not allowing supplement manufacturers to make disease claims is rightly viewed as based on the need to protect consumers with respect to conditions needing medical evaluation and care. FDA also viewed as implied disease claims statements promoting use "for a serious health condition that is beyond the ability of the consumer to evaluate." This is one of the guidelines in the report of the Commission on Dietary Supplements (CDSL), a Commission on which I served.

The claim of usefulness for ordinary morning sickness, if looked at in isolation for its effects on the mother, might seem to be a matter within the consumer's ability to judge. However, in the context of a pregnancy, a claim that a product can be used specifically to treat a condition that relates to pregnancy carries the implication that the product will not harm the unborn child. The ability of the product to harm the fetus is beyond the ability of the mother to know when the product is used. She will find out, but too late. If the child suffers birth defects, the results are tragic. Thus, I believe this claim should be considered a disease claim. The manufacturer should have to meet the more demanding requirements governing drugs to provide the best assurance that the product will not cause this type of grave harm.

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If the product is regarded as a supplement, there will be no pre-market approval of the safety testing done for the supplement. I have recommended in the CDSL Report, page 25, that supplements bear warnings if the safety of the supplement has not been substantiated by adequate tests. If morning sickness remains classified as a supplement claim, these products should be made subject to this type of warning requirement. The need for testing is at the highest level for claims posing a risk of birth defects.

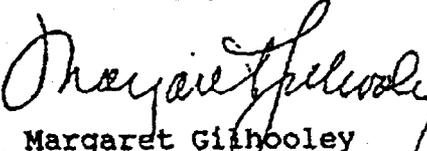
The CDSL Report recommended that supplement manufacturers recognize the need to advise pregnant women on the need to consult a health professional about supplement use. CDSL Report, p. 26. This recommendation, sound as it is, is not sufficient for these claims. The product is making a claim that specifically encourages use during pregnancy. Moreover, the physician or other health professional is likely to have no way to know what testing has been done on the supplement to determine its potential to cause birth defects. The physician cannot evaluate the appropriateness of use during pregnancy unless the testing for the product is publicly accessible. Moreover, the testing should have significant scientific support, given the health consequences at stake. See the FTC's criteria for what is adequate substantiation of the effectiveness of claims, criteria which reflect the health importance of the claim.

The better approach to protect the public health with respect to claims for morning sickness is to classify the claim as a disease claim. That classification will ensure the greatest degree of protection of the unborn child. It also reflects the expectation that the expectant mother has that the product is intended not to cause harm to the child.

I urge FDA to reopen the rulemaking proceeding, or issue a revised statement of its position, so that the agency will make clear that it regards a claim for use for morning sickness as a disease claim.

Please let me know if I can provide more information about this matter.

Sincerely yours,

  
Margaret Gilhooley  
Professor of Law