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February 2, 2000

Jane Henney, M.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Final FDA Regulations on Claims Made for Dietary Supplements
Concerning the Effect of the Product on the Structure or Function of
the Body

Dear Commissioner Henney:

I am writing to urge that you make changes concerning uses during pregnancy in the final rule concerning dietary supplements published on January 6, 2000. The rule is scheduled to go into effect on February 7, 2000. As a former member of the Food and Drug Administration Fertility and Maternal Health Drugs Advisory Committee, I feel strongly that drugs taken in the first trimester of pregnancy should be tested for safety.

The rule categorizes ordinary morning sickness and leg edema associated with pregnancy as common conditions that are not "diseases." Under the Dietary Supplement Health Education Act (DSHEA), that categorization allows dietary supplement manufacturers to promote products as treatments of those conditions without first proving that the products are safe and effective. We strongly disagree with that categorization. Both morning sickness and edema of pregnancy, when uncomfortable enough to cause a woman to use a substance for relief of symptoms, are severe enough to be considered diseases, and are often treated with drugs. We urge you immediately to amend the rule explicitly to include morning sickness and edema of pregnancy as diseases.

We, therefore, urge you immediately to revoke those parts of the rule that reclassify as non-diseases morning sickness and edema of pregnancy. We appreciate your prompt reply to this urgent request.

Sincerely yours,

Jennifer R. Niebyl, M.D.
Professor and Head

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